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No. 02-1845

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

AETNA HEALTH INC.,

Petitioner,

v.

JUAN DAVILA,

Respondent.

On Writ Of Certiorari
To The United States Court Of Appeals
For The Fifth Circuit

BRIEF FOR PETITIONER AETNA HEALTH INC.

JOHN B. SHELY
KENDALL M. GRAY
ANDREWS & KURTH LLP
600 Travis, Suite 4200
Houston, Texas 77002
(713) 220-4200

ROY T. ENGLERT, JR.
ROBBINS, RUSSELL,
ENGLERT, ORSECK &
UNTEREINER LLP
1801 K Street, N.W.
Washington, D.C. 20006
(202) 775-4500

MIGUEL A. ESTRADA
Counsel of Record
MARK A. PERRY
WILLIAM M. JAY
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 955-8500

J. EDWARD NEUGEBAUER
AETNA HEALTH INC.
980 Jolly Road (U19A)
Blue Bell, PA 19422
(215) 775-5939

Counsel for Petitioner

QUESTION PRESENTED

Whether the Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001 *et seq.* ("ERISA"), as construed by this Court in *Pilot Life Insurance Co. v. Dedeaux*, 481 U.S. 41 (1987), and its progeny, completely preempts state-law claims by ERISA plan participants or beneficiaries who assert that a managed care company tortiously "failed to cover" (*i.e.*, pay for) medical care.

PARTIES TO THE PROCEEDINGS

Petitioner Aetna Health Inc. is the successor to Aetna U.S. Healthcare Inc. and Aetna U.S. Healthcare of North Texas Inc., both of which merged into Aetna Health Inc. In addition to the parties named in the caption, the following individuals and entities were parties in the consolidated cases below and are respondents in this Court. The following parties were defendants-appellees in the court below: Cigna Healthcare of Texas, Inc., d/b/a Cigna Corporation (petitioner in No. 03-83); Humana, Inc.; Humana Health Plan of Texas, Inc., d/b/a Humana Health Plan of Texas (Dallas), d/b/a Humana Health Plan of Texas (San Antonio), d/b/a Humana Health Plan of Texas (Corpus Christi); and Humana HMO Texas, Inc. The following party was a plaintiff-appellant-cross-appellee in the court below: Ruby R. Calad (named respondent in No. 03-83). The following parties were plaintiffs-appellants below: Robert Roark; and Robert Roark, on behalf of the estate of Gwen Roark. The following party was a plaintiff-cross-appellee in the court below: Walter Patrick Thorn.

RULE 29.6 STATEMENT

The corporate disclosure statement included in the petition for a writ of certiorari remains accurate.

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BRIEF FOR PETITIONER AETNA HEALTH INC.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-29a) is reported at 307 F.3d 298 (5th Cir. 2002). The opinion and order of the district court (Pet. App. 30a-35a) is unreported.

JURISDICTION

The district court had federal question jurisdiction over the plaintiff's claims pursuant to 28 U.S.C. § 1331 and the complete preemption effected by 29 U.S.C. § 1132. The court of appeals had jurisdiction to review the final judgments of the district court pursuant to 28 U.S.C. § 1291. The judgment of the court of appeals was entered on September 17, 2002. The court of appeals denied Aetna's petition for rehearing and suggestion for rehearing en banc on April 15, 2003. Pet. App. 37a-39a. The petition for a writ of certiorari was filed on June 20, 2003, and granted on November 3, 2003. 124 S. Ct. 462 (2003). This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the Constitution, U.S. CONST. art. VI, cl. 2; Sections 502 and 514 of the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §§ 1132 and 1144; and the Texas Health Care Liability Act ("THCLA"), TEX. CIV. PRAC. & REM. CODE ANN. §§ 88.001-.003, are set forth in the Petition Appendix at 41a-63a. Section 503 of ERISA, 29 U.S.C. § 1133, and the associated regulation, 29 C.F.R. § 2560.503-1, are set forth in the appendix to this brief.

STATEMENT OF THE CASE

Respondent Juan Davila, a participant in an employee health benefit plan insured by petitioner Aetna Health Inc. ("Aetna"), sued Aetna under Texas law for damages allegedly resulting from a medication that his doctor prescribed after Aetna, in accordance with the terms of the plan, determined that coverage was not available for a different medication. Aetna removed the action to federal district court, which concluded that Davila's state-law claims were completely preempted by the Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001 *et seq.* ("ERISA"). The court of appeals reversed, holding that Davila's claims were not preempted because they did not "duplicate" ERISA's remedial scheme.

1. ERISA's remedial scheme consists primarily of two statutory sections, ERISA §§ 502(a) and 503, 29 U.S.C. §§ 1132(a) and 1133. Section 503 and its implementing regulation (29 C.F.R. § 2560.503-1) require an ERISA plan to maintain elaborate procedures for beneficiaries to appeal adverse benefit determinations within the plan's administrative structure. If that internal appeal fails, Section 502(a) allows beneficiaries to go to court to ensure compliance with the terms of the plan and to obtain specified forms of relief—prospective and retrospective—for any failure to comply.

Under Section 502(a), a beneficiary may seek advance clarification of coverage before incurring the expense he wishes the benefit plan to cover. Alternatively, a beneficiary may seek relief after the fact by bringing an action for benefits due under the plan or for "appropriate equitable relief," together with a reasonable attorney's fee, but he cannot recover consequential or punitive damages. *See generally Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 52-53 (1987).

In *Pilot Life*, this Court held that Section 502(a)'s remedial scheme is exclusive and preempts any additional or supplemental state-law remedies for conduct governed by ERISA. 481 U.S. at 52. In *Metropolitan Life Insurance Co. v. Taylor*, 481 U.S. 58 (1987), this Court held that any state-law claim that falls within Section 502(a)'s preemptive scope is removable to federal court because it necessarily states a federal question. *Id.* at 67.

2. Most Americans receive health coverage through employer-provided benefit plans, which are regulated by ERISA. Although ERISA subjects benefit plans to a uniform national regulatory framework, it also allows employers considerable flexibility in designing the type of health plan and the specific benefits they make available to their employees. *E.g.*, *Lockheed Corp. v. Spink*, 517 U.S. 882, 887 (1996). Employers generally use a competitive "request for proposals" ("RFP") process to select the plan's insurer (or, in the case of employers with self-funded plans, an insurance company that offers supportive administrative services). Insurance companies compete to provide these services, tailoring the details of their proposals to employers—from the scope of covered services to the rules for eligibility—to achieve the combination of costs and coverage that the particular employer desires. Even relatively simple changes in the scope of desired coverage can significantly change the cost, making the employer's expectation as to the scope of coverage, limitations, and exclusions particularly important in the bidding process. *See, e.g.*, David M. Studdert et al., *Expanded Managed Care Liability: What Impact on Employer Coverage*, HEALTH AFFAIRS, Nov./Dec. 1999, at 20.

A common model is the health maintenance organization (HMO), which carefully emphasizes preventive care and provides incentives or restrictions to participants to obtain care and services within a contracted network of health care providers.[1] This structure decreases the need to treat pre-

[1] In a "network model" HMO, such as Aetna's, the HMO itself does not provide medical care. Rather, the HMO contracts

ventable conditions, limits incentives to undergo unnecessary procedures, and improves predictability, allowing the employer to secure from insurers, such as Aetna, discounted prices in the RFP process.[2] In the principal alternative, a fee-for-service or full indemnity plan charges employers (and, thus, employee-beneficiaries whom the employers ask to contribute to defray the costs of health coverage) a considerably higher premium and in return generally offers a broader range of coverage with fewer exclusions and limitations and fewer or no provider network restrictions. *See generally* PAUL J. FELDSTEIN, HEALTH POLICY ISSUES 161-66

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with a network of treating physicians (often referred to as "participating providers") who agree to provide services to HMO members according to established fee schedules. Under the network model, the treating physician is independent of the HMO, and his treatment decisions are not bound by any coverage determination that the HMO may make for the purpose of deciding whether the employer's plan will pay for the proposed treatment. By contrast, physicians in a "group model" or "staff model" HMO make both coverage and treatment decisions. Group-model HMOs are owned or operated by physicians, and staff-model HMOs retain the physicians as salaried employees—rather than independent contractors—of the HMO. Thus, group- and staff-model HMOs provide medical care themselves. And the treating physicians are also responsible for making coverage determinations. *See, e.g.*, 1 BARRY R. FURROW ET AL., HEALTH LAW § 9-11, at 500 (2d ed. 2000); STEVEN J. SACHER ET AL., EMPLOYEE BENEFITS LAW 1076 & n.322 (2d ed. 2000); *see also Pegram v. Herdrich*, 530 U.S. 211, 216 n.3 (2000). Because the physicians provide care exclusively through the HMO (and *vice versa*), the treating physician may not be able to recommend treatment that the HMO cannot provide.

[2] Indeed, reducing unnecessary procedures may have the additional salutary effect of reducing the ensuing complications. *Pegram*, 530 U.S. at 221; *see, e.g.*, Ching-To Albert Ma & Michael H. Riordan, *Insurance, Moral Hazard, and Managed Care*, 11 J. ECON. & MGMT. STRATEGY 81 (2002).

(1994); 1 BARRY R. FURROW ET AL., HEALTH LAW § 9-10, at 505-06 (2d ed. 2000). Both HMOs and fee-for-service models use some form of managed care techniques to control health costs and keep premiums at predictable levels. When designing the health plan that they will offer their employees, employers may determine which managed care techniques to apply.

Managed care techniques take various forms, but the most common element is the process of prospective "utilization review," which controls costs by eliminating unnecessary expenditures and by carefully delimiting the scope of coverage to favor those procedures that are both necessary and cost-effective. Indeed, almost every form of employer-provided health plan now includes some element of utilization review. FELDSTEIN, *supra*, at 162-63.

Managed care strategies require the companies that perform utilization review for an employee health benefit plan to differentiate between covered and uncovered services each time a participant presents a claim for benefits (or, if required under the plan, requests precertification of coverage). Those companies make these decisions by interpreting the plan documents, which regulate the scope of coverage both through specific exclusions—such as a declaration that chiropractic care is never covered—and through a general contract term requiring that services be "medically necessary" in order to be covered. 1 FURROW, *supra*, § 9-2, at 473-74.[3] "Medical necessity" is a term of art that each plan document defines individually. Generally, such definitions incorporate

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[3] "[I]nsurance contracts do not have to contain such guarantees, and not all do. Some, for instance, guarantee medically necessary care, but then modify that obligation by excluding experimental procedures from coverage." *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 380 n.10 (2002) (citing *Tillery v. Hoffman Enclosures, Inc.*, 280 F.3d 1192 (8th Cir. 2002)).

economic considerations as well as medical ones: a "medically necessary" procedure or treatment often is defined as one that is not only medically appropriate, but also more cost-effective than any other, equally appropriate procedure or treatment. *E.g.*, J.A. 54-55. In the context of prescription drug coverage, which becomes prohibitively expensive without cost controls, employer plan sponsors seek RFPs that either exclude certain expensive drugs from coverage or pay for such drugs only after more economical alternatives fail, often through a detailed listing known as a "formulary." *See, e.g.*, Stephan L. Burton et al., *The Ethics of Pharmaceutical Benefit Management*, HEALTH AFFAIRS, Sept./Oct. 2001, at 150, 154.

3. Davila is employed by Monitronics International Inc., a burglar-alarm company. Pet. App. 67a. Monitronics is one of the many employers in Texas that contract with Aetna to insure and help administer its employee health benefit plan. In a Group Agreement effective December 1, 1999, Aetna contracted to provide insurance coverage for Monitronics employees participating in the company's health plan, which is an employee welfare benefit plan governed by ERISA. J.A. 25. Davila was a participant in the Monitronics Plan. *Id.* at 15.

Under the agreement, Aetna provides administrative services to the Monitronics Plan: it reviews requests for coverage and pays providers—*e.g.*, doctors, hospitals, nursing homes, pharmacists, and the like—who perform covered services for members. J.A. 34-35 ("[Aetna] has complete authority to review all claims for Covered Benefits .... [Aetna] shall have discretionary authority to determine whether and to what extent eligible individuals and beneficiaries are entitled to coverage ...." (boldface omitted)). In this network-model HMO, Aetna does not itself provide any medical services; the professionals who provide services to plan members are "independent contractors," not Aetna em-

ployees, and it is those professionals who are "solely responsible for any health services rendered." *Id.* at 31.

The Monitronics Plan details the benefits to which participants and other beneficiaries may be entitled, and it specifies that Aetna will not approve benefits for any service that is not "Medically Necessary" as defined in the plan documents.[4] Under the plan, medical necessity includes both medical criteria and cost-based factors: in general, a "medically necessary" service is one that is both "as likely to produce a significant positive outcome as ... any alternative service or supply," and "no more costly ... than any equally effective service or supply." J.A. 54-55.

The plan documents reiterate that Aetna's coverage determinations do not control the treating physician's recommendation or prevent a beneficiary from following a prescribed course of treatment that does not meet the contractual definition of "medical necessity." The definition of medical necessity, the plan specifies, is only "[f]or the purpose of coverage." J.A. 54. Coverage denotes payment by the plan, and lack of coverage does not preclude a plan member from receiving a non-covered service through other means. To this end, the Monitronics Plan's Certificate of Coverage emphasizes in bold print: "**THIS CERTIFICATE APPLIES TO COVERAGE ONLY AND DOES NOT RESTRICT A MEMBER'S ABILITY TO RECEIVE HEALTH CARE SERVICES THAT ARE NOT, OR MIGHT NOT BE, COVERED BENEFITS UNDER THIS CERTIFICATE.**" *Id.* at 40; *see also id.* at 106-07, 108. The Moni-

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[4] The plan contains certain specific exceptions under which it expressly covers certain services, such as an annual mammogram, even when they are *not* medically necessary as defined by the plan. J.A. 58. The plan also excludes various expenses—such as blood plasma and experimental drugs—from the scope of coverage regardless of medical necessity. *Id.* at 70, 76.

tronics Plan also makes clear that "[i]f the Member's [treating physician] performs, suggests, or recommends a Member for a course of treatment that includes services that are not Covered Benefits, the entire cost of any such non-covered services will be the Member's responsibility." *Id.* at 46 (boldface omitted).

A rider to the Monitronics Plan governs prescription drug coverage. The rider does not alter the definition of medical necessity, and further specifies that prescription drugs are covered only as "indicated . . . for a medical condition as determined by" Aetna. J.A. 141. Pursuant to the rider, Aetna maintains a formulary listing the terms under which prescription medications are covered. App., *infra*, 26a-40a.[5] Under the formulary, certain expensive medications are subject to precertification requirements (*i.e.*, coverage must be approved before the prescription can be filled at the insured rate) and/or a "step-therapy program" (*i.e.*, alternative, less expensive medications will be covered first unless they are contraindicated). *See id.* at 30a, 34a.

4. Davila consulted his physician, Dr. Joseph Lopez, for treatment of pain associated with arthritis. Dr. Lopez prescribed Vioxx, an anti-inflammatory medication, and sought precertification for the Vioxx prescription from Aetna. Pet. App. 77a.[6] In a letter to Dr. Lopez, an Aetna pharmacologist explained that Vioxx appears on the prescription drug formulary only conditionally. *Id.* at 80a-81a. Under the formulary's step-therapy program, Vioxx is a covered plan benefit

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[5] Although the formulary was cited in the complaint, it was not included in the certified record below. Davila does not oppose the inclusion of relevant excerpts in the appendix to this brief.

[6] Vioxx was then new to the market and the subject of massive marketing efforts. *See, e.g.*, Janice Rosenberg, *Head to head struggle: Initial Celebrex, Vioxx ad spending, sales stunning*, ADVERTISING AGE, Apr. 3, 2000, at S2.

only if the member has already tried—or cannot try, because of allergy or contraindication—at least two of the fifteen other, similar drugs that are listed unconditionally on the formulary. *Id.* at 80a; *see* App., *infra*, 29a-30a, 40a. The letter to Dr. Lopez also reminded him that Davila could submit a grievance to Aetna challenging the decision, or appeal Aetna's coverage determination to an Independent Review Organization (IRO). Pet. App. 81a. *See generally Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 359, 361 (2002) (discussing state laws providing for IRO appeals). Either the internal grievance or the IRO appeal could have been expedited if Davila's condition had been life-threatening. Pet. App. 81a; J.A. 93, 94-95.

Davila's complaint reveals that he did not avail himself of *any* of the several options available to him if he or Dr. Lopez thought Vioxx was more appropriate than any of the fifteen alternative medications. He did not represent to Aetna that he had a "contraindication, intolerance, [or] allergy" that made it inadvisable to prescribe one or more of the Vioxx alternatives listed on Aetna's formulary. He did not file a grievance with Aetna or invoke his statutory right to an IRO appeal. And he did not file an action under ERISA § 502(a)(1)(B) to compel Aetna to pay for Vioxx under the Monitronics Plan. *See* Pet. App. 70a. Moreover, Davila chose not to pay to have the original Vioxx prescription filled while seeking coverage. Instead, Dr. Lopez prescribed Naprosyn—one of the fifteen anti-inflammatory medications listed on the formulary as less expensive alternatives to Vioxx—for Davila's arthritis. *See id.* at 68a; App., *infra*, 29a-30a, 40a. Several weeks later, Davila was hospitalized and diagnosed with bleeding ulcers. Pet. App. 68a.

Davila claimed that the ulcers were caused by the Naprosyn prescribed by Dr. Lopez and that they would not have occurred had he taken Vioxx instead. But he did not sue Dr. Lopez for malpractice for prescribing Naprosyn. In-

stead, he sued Aetna in Texas state court for following the plan formulary and declining to pay for Vioxx until Davila's physician had either tried another medication or determined that the covered alternatives were contraindicated by Davila's condition. Pet. App. 68a-69a. Davila's complaint asserted claims under the Texas Health Care Liability Act ("THCLA"), TEX. CIV. PRAC. & REM. CODE §§ 88.001-.003, a recently enacted state statute that purports to authorize suits against HMOs based on the medical treatment provided to their members. Davila demanded consequential and punitive damages and a jury trial. Pet. App. 70a-71a, 74a.

a. Aetna removed the action to the United States District Court for the Northern District of Texas, asserting that Davila's claims were completely preempted by ERISA as construed in *Pilot Life*, and thus were removable under *Metropolitan Life*. Pet. App. 89a. Davila asserted that subsequent decisions by this Court had undermined the complete preemption rule articulated in *Pilot Life* and *Metropolitan Life*, and he moved to remand based on lack of subject matter jurisdiction. The district court denied the motion, concluding that "[w]hat Plaintiff really challenges . . . is Defendants' determination regarding which particular drugs are covered under the plan and the circumstances of that coverage." *Id.* at 34a.[7] Therefore, Davila's claims "concern[ed] the administration of benefits under the plan." *Id.* Accordingly, under *Metropolitan Life*, Davila's claims had to be recharacterized as federal. *Id.* Because Davila expressly refused to proceed with a claim for benefits under ERISA, the district court then dismissed the action with prejudice. *Id.* at 34a-35a.

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[7] Although Davila's complaint contained a conclusory allegation that Aetna provided medical services (Pet. App. 69a), the district court determined from the plan documents, Dr. Lopez's affidavit, and Davila's own recitation of the facts that Davila's claims actually involved benefits administration. *See id.* at 34a.

b. On appeal, the Fifth Circuit consolidated Davila's case for argument with those of several other individuals who had sued HMOs under the THCLA, including Ruby Calad, the respondent in the consolidated case (No. 03-83). The court of appeals reversed the dismissal of both Davila's and Calad's actions. The court did not examine whether the state-law claims Davila and Calad asserted, or the remedies they sought, impermissibly *supplemented* the exclusive remedial scheme set out in Section 502(a). Instead, it confined its analysis to whether a THCLA claim precisely "duplicates" any provision of Section 502(a)—an inquiry that it answered in the negative. Pet. App. 9a, 10a-20a.

According to the court of appeals, Section 502(a)(3) could not preempt respondents' THCLA claims, because that provision allows "only those categories of remedies that were typically available in equity, *not the damages claims Calad and Davila bring*." Pet. App. 10a (emphasis added) (citation and internal quotation marks omitted). For similar reasons, the Fifth Circuit thought that Section 502(a)(1)(B) could not preempt the state-law causes of action: The THCLA claims, the Fifth Circuit wrote, were more in the nature of actions in tort, whereas Section 502(a)(1)(B) is akin to an action for breach of contract. Pet. App. 16a-17a. Finally, the court of appeals relied on this Court's decision in *Pegram v. Herdrich*, 530 U.S. 211 (2000), for the proposition that the THCLA claims did not overlap with ERISA § 502(a)(2), which permits actions for breach of fiduciary duty. Although the Fifth Circuit conceded that "*Pegram* did not decide the precise question before us," the court concluded that "its holding is broad enough to apply here," because evaluating Davila's assertion that he should have received coverage for Vioxx involves "the type of 'when and how' medical necessity questions . . . that fall within" what the court took to be "*Pegram*'s rule." Pet. App. 12a, 14a. The court accordingly held that Davila's claims were not completely preempted and

thus did not confer removal jurisdiction. *See* Pet. App. 20a, 29a.[8]

SUMMARY OF ARGUMENT

I. Under *Pilot Life Insurance Co. v. Dedeaux*, 481 U.S. 41 (1987), and its progeny, both Davila's state-law claims challenging Aetna's administrative determination that Vioxx was not covered under the Monitronics Plan and the remedies he seeks are preempted by ERISA.

A. This Court has repeatedly, and unanimously, held that ERISA's remedial provisions are not subject to supplementation by state law, and that any state-law remedy that offers plan participants a form of relief not available under ERISA is completely preempted.

1. This Court has recognized on numerous occasions that the causes of action and forms of relief available under ERISA are carefully balanced to fit the circumstances that Congress intended to address. *E.g.*, *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 210 (2002); *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 252 (1993). Given the complexity of the subject matter and the compromises inherent in regulating pension and welfare benefit plans, the Court has held that remedies and rights of action not expressly set forth in ERISA § 502(a) are affirmatively foreclosed. *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 146 (1985). Accordingly, federal courts in ERISA actions may not award remedies not specifically authorized by the statute, such as consequential or punitive damages.

2. In *Pilot Life*, this Court made clear that the States likewise may not disturb the careful balance struck by Con-

[8] The case was subsequently remanded to Texas state court, where it has remained in abeyance pending this Court's ruling on the petition for a writ of certiorari and now on the merits.

gress by authorizing additional remedies for conduct actionable under ERISA (or by providing a right of action for conduct not actionable under ERISA). The Court held that a common-law claim for "bad faith" denial of benefits under a disability plan sought "remedies for the improper processing of a claim for benefits under an ERISA-regulated plan"—remedies "that Congress rejected in ERISA." 481 U.S. at 57. That same day, the Court held in *Metropolitan Life Insurance Co. v. Taylor*, 481 U.S. 58 (1987), that ERISA § 502(a)'s preemptive force is so strong that any claim within its scope must be recharacterized as a federal action under ERISA and can be removed to federal court.

ERISA's remedial provisions strike a balance between competing interests, facilitating the swift and inexpensive recovery of benefits while affording plan administrators a degree of certainty and predictability that allows them to hold down costs. As the Court recognized in *Pilot Life* and *Metropolitan Life*, that closely interwoven compromise would unravel if state law were permitted to impose varying standards of care on plan administrators or authorize damage awards in the context of benefits administration. Thus, any state-law cause of action or remedy that would supplement ERISA § 502(a) is preempted.

3. In *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133 (1990), the Court unanimously confirmed that the remedies available under ERISA § 502(a) are the exclusive means of redressing ERISA-protected rights. The Court held preempted a state-law action that sought to supplement the ERISA remedies. And in *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002), all nine Members of the Court agreed that ERISA preempts any state law that gives plan participants a "new cause of action" or a "new form of ultimate relief."

B. Davila's complaint is that Aetna failed to approve coverage for Vioxx. Any contention that Vioxx was a cov-

ered medication under the terms of the Monitronics Plan, such that Aetna's failure to approve coverage was a violation of the plan, could be brought under ERISA § 502(a)(1)(B), which authorizes participants to sue to enforce the terms of the plan. Accordingly, Davila's state-law action would necessarily supplement the ERISA remedy, and is preempted under *Pilot Life*. Conversely, if Davila means to contend that Aetna had a duty to approve coverage for Vioxx notwithstanding the terms of the Monitronics Plan, any such contention would conflict with the plan itself. *Pilot Life* likewise preempts such a state-law action, which would impose duties on Aetna that are inconsistent with Aetna's obligations under ERISA.

II. The Fifth Circuit conceded that *Pilot Life* "arguably supports" Aetna's construction of ERISA § 502(a), but nevertheless held that Davila's state-law claims are not preempted by ERISA. Pet. App. 19a. In so doing, the court misread this Court's decision in *Pegram v. Herdrich*, 530 U.S. 211 (2000), and erroneously looked to a series of cases involving ERISA § 514.

A. The court of appeals concluded that because Aetna declined to cover Vioxx under the Monitronics Plan's "medical necessity" limitation, Aetna's decision was a so-called "mixed question of treatment and eligibility" that could be challenged under state law. This was a clear misreading of *Pegram*.

1. *Pegram* involved an action under ERISA for breach of fiduciary duty. Unlike the HMO in this case, the HMO in *Pegram* was owned and operated by the treating physicians. The Court held that when such physicians—the co-owners of the HMO—make "mixed eligibility and treatment decisions," they cannot be sued for breach of fiduciary duty under ERISA.

2. Unlike the physician co-owners of the group-model HMO at issue in *Pegram*, administrators of network-model

HMOs (such as Aetna's) do not make treatment decisions. The "mixed questions" referred to in *Pegram* simply do not exist outside the context of group- or staff-model HMOs, because network-model HMOs do not "act[] through their physicians." *Pegram*, 530 U.S. at 231. As the Solicitor General has explained, "[t]he better reading of *Pegram* . . . is that it addresses only mixed decisions made by *treating* physicians." Brief for the United States as *Amicus Curiae* at 8, *Rush Prudential HMO, Inc. v. Moran*, No. 00-1021 (Nov. 7, 2001). Where, as here, the insurer provides no treatment, there is nothing "mixed" about its decision; the decision is a benefits determination that can be challenged only under ERISA.

3. This understanding is confirmed by *Metropolitan Life*, in which the Court recognized that the plaintiff's claims involved benefits administration even though the administrator's decision had a medical component. Similarly, in *Black & Decker Disability Plan v. Nord*, 123 S. Ct. 1965 (2003), this Court recognized that coverage decisions are administrative even where the insurer takes into account medical evidence.

B. The complete preemption doctrine under ERISA § 502(a) is distinct from the preemption inquiry under ERISA § 514, which preempts state laws that "relate to" ERISA plans. Conflating the two inquiries, as the court of appeals apparently did, is a structural misapplication of ERISA.

This Court has consistently separated the complete preemption and defensive preemption inquiries. *E.g.*, *Ingersoll-Rand*, 498 U.S. at 142. In *Boggs v. Boggs*, 520 U.S. 833 (1997), for example, the Court held preempted state statutes that conflicted with individual provisions of ERISA, and expressly discounted the need to analyze the preemption claim under Section 514.

For this reason, recent cases tracing the outer boundaries of Section 514 are not instructive in applying Section 502.

Section 514 is so broad and potentially indeterminate that Congress may have intended the courts to define the outer limits of defensive preemption. Section 502, by contrast, is written with sufficient specificity to overcome the presumptions that have motivated this Court's Section 514 cases. *See Metropolitan Life*, 481 U.S. at 64, 66.

III. *Pilot Life* has been the law for nearly two decades, and there is no basis in law or policy for this Court to overrule it.

A. The *Pilot Life* line of cases further ERISA's goal of ensuring a flexible, uniform, and predictable system of benefit-plan regulation. The Nation's system of employer-provided health insurance has grown up in reliance on that framework, and this Court should not disrupt those settled expectations by now suddenly reversing course.

1. *Stare decisis* is strongest when, as here, Congress has left this Court's decisions undisturbed despite repeated reexamination of the subject area. Indeed, in enacting ERISA, Congress echoed and approved an earlier line of decisions by this Court that took a similarly robust approach to preemption under the Labor-Management Relations Act. This case in no way presents the sort of special justification needed to justify departing from a statutory-interpretation decision that has been clearly and consistently applied.

2. Virtually the entire system of employer-provided health benefits coverage has taken shape in reliance on *Pilot Life* and its progeny. Employers have embraced managed care, and the network-model HMO in particular, precisely because by confining the managed care entity's duties to claims administration, they subject it to ERISA's "uniform standards of primary conduct" and "uniform regime of ultimate remedial orders." *Rush Prudential*, 536 U.S. at 379. Managed care entities have set the prices they charge for their services accordingly. Subjecting those companies (and potentially others) to state-law standards that would override

the custom-designed terms of an employer's benefit plan would completely upset those pricing decisions, effectively requiring those companies (and employers) to offer a full-indemnity plan to participants who never had to shoulder the considerable costs associated with that form of coverage.

B. This Court's decision in *Pilot Life* leaves ample room for patient-protection regulation on both the federal and state levels. Congress, the States, and individual customers have already brought about pro-patient changes in employee health benefits—without disrupting the exclusivity of the judicial remedies that ERISA makes available.

1. Employers can use bargaining power with HMOs to dictate more generous medical-necessity criteria in ERISA plans. Likewise, both Congress and the States can and do mandate the inclusion of certain coverage terms in health benefit plans—terms that are judicially enforceable under the current ERISA framework. And, in limited circumstances, States may make available *nonjudicial* safeguards, such as the independent review that this Court approved in *Rush Prudential*, without opening the door to new and severe damages awards like the one Davila seeks.

2. Affirming the decision below and allowing plaintiffs like Davila to obtain such supplemental remedies would utterly undo the uniformity, predictability, and certainty that the *Pilot Life* line of decisions secures. Any such decision by this Court would swiftly and surely lead to further increases in the already high costs that employers and employees pay for health care. Such a decision, which would directly affect millions of workers and an entire sector of the American economy, is indubitably a legislative one. Davila and his supporters should address their challenge to *Pilot Life*—and to the system of employee benefits that relies on it—to Congress, not to this Court.

ARGUMENT

I. Davila's State-Law Tort Claims Would Frustrate ERISA's Remedial Exclusivity And Therefore Are Completely Preempted Under *Pilot Life*

The only dispute in this case is whether an action against Aetna based on its role in approving or disapproving the payment of benefits under the Monitronics Plan is a supplemental form of recovery that conflicts with, and thus is completely preempted by, ERISA's exclusive remedial provision. Under any reading of this Court's decisions construing Section 502(a), Davila's claims are completely preempted. Section 502(a) provides the sole means of relief for plaintiffs challenging benefits-administration decisions, and may not be supplemented by state-law remedies. The conduct that Davila challenges was plainly benefits administration: Aetna's sole interaction with Davila was in determining eligibility for benefits under the Monitronics Plan, and Davila's dispute with Aetna turns on whether Aetna, in performing claims-administration functions for the plan, should have approved his request for immediate coverage of Vioxx. The remedies that Davila seeks—compensatory and punitive damages—are not available in an ERISA action challenging the conduct in question. Davila's attempt to circumvent Section 502(a)'s careful limitation on permissible remedies is precisely what *Pilot Life* and its progeny foreclose.

A. Section 502(a) Provides A Comprehensive And Exclusive Means Of Enforcing Beneficiaries' Rights Under ERISA Plans

In an unbroken string of decisions, this Court has consistently concluded from ERISA's text, structure, and legislative history that ERISA's comprehensive remedial scheme forecloses additional state-law remedies. In the last seventeen years, the Justices of this Court have *unanimously* agreed on *four* separate occasions that ERISA's remedial

provisions are not subject to supplementation by state law, and that *any* alternative state-law remedy that offers plan beneficiaries a form of judicial relief not permitted by ERISA is completely preempted. *Pilot Life Insurance Co. v. Dedeaux*, 481 U.S. 41, 54 (1987); *Metropolitan Life Insurance Co. v. Taylor*, 481 U.S. 58, 62-63 (1987); *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 144-45 (1990); *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 379 (2002); *id.* at 388 (Thomas, J., dissenting) (agreeing with the Court majority on this point). Davila's action for damages under the THCLA is precisely the sort of impermissible state-law alternative that, under those cases, is preempted by ERISA, and the Fifth Circuit therefore erred in ordering Davila's state-law claims revived and remanded.

1. The Fifth Circuit's analysis was flawed chiefly because it neglected to analyze ERISA's *exclusive* remedial scheme as a whole, and instead focused only on whether Davila's THCLA claims precisely "duplicate[d]" individual rights of action or remedies expressly available under ERISA.[9] This Court's complete-preemption cases, however, turn on an understanding of the *overall* structure of ERISA's remedial scheme, including the remedies it forecloses as well as those it authorizes. The teaching of those cases is that preemption turns not on whether a state law duplicates an ERISA cause of action, but on whether the state law gives ERISA-plan participants a right of action or a remedy that Congress omitted from ERISA.

As this Court has recognized on numerous occasions, both the causes of action and the forms of relief available under Section 502(a) are carefully balanced and meticulously circumscribed to fit the circumstances that Congress intended to address. *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 252

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[9] As CIGNA notes, the Fifth Circuit's "duplication" analysis was based on a misreading of *Ingersoll-Rand*. CIGNA Br. 18.

(1993) (ERISA is "an enormously comprehensive and detailed statute that resolved innumerable disputes between powerful competing interests—not all in favor of potential plaintiffs"). For example, a beneficiary aggrieved by the incorrect denial of benefits due under the plan may recover the benefits denied him. ERISA § 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B). The other actions are likewise limited. Even the most flexible remedial provision in Section 502(a)—subdivision (3)(B), which permits an action for "appropriate equitable relief"—contains limiting language that permits a federal court to award only certain core forms of relief that were "'*typically* available in equity.'" *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 210 (2002) (quoting *Mertens*, 508 U.S. at 256).

Most significantly, Section 502(a)(1)(B) does not permit the award of legal relief—such as consequential and punitive damages other than withheld benefits. *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 144 (1985) (Section 502(a)(1)(B) "says nothing about the recovery of extracontractual damages"). Consequential relief and punitive damages are not listed among the few forms of monetary relief that ERISA specifically makes available (such as benefits or statutory penalties).[10] Nor does Section 502(a)(3)(B) authorize awards of compensatory or punitive damages; that provision allows only "appropriate *equitable* relief," whereas "[m]oney damages are, of course, the classic form of legal relief" and are therefore precluded. *Mertens*, 508 U.S. at

[10] Section 502 permits a beneficiary to recover a monetary award in his own right—not the plan's—only in limited forms: a civil penalty against an administrator who does not comply with disclosure requirements, or benefits due under the plan. *See* ERISA § 502(a)(1)(A), (a)(1)(B), (c), 29 U.S.C. § 1132(a)(1)(A), (a)(1)(B), (c); *see also Russell*, 473 U.S. at 144 (only the plan may recover "appropriate relief" under Section 502(a)(2) for a fiduciary's breach of duty).

255; *accord, e.g.*, *Great-West*, 534 U.S. at 234 (Ginsburg, J., dissenting) (agreeing that Section 502(a)(3)(B) should be construed to retain the "large limitation" that "exclude[s] compensatory and punitive damages").

Given the complexity of the subject matter and the extensive study to which Congress devoted its comprehensive regulation of that area in ERISA, this Court has appropriately determined that remedies and rights of action not specifically enumerated in Section 502(a) were affirmatively foreclosed, not merely forgotten, by Congress. Section 502(a)'s "carefully integrated civil enforcement provisions" are "strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly." *Russell*, 473 U.S. at 146. Likewise, Congress's expansion of the class of potential fiduciary defendants from what the common law would have allowed counterbalances its limitation of the remedies available against those defendants. *Mertens*, 508 U.S. at 262. For this reason, this Court has been "especially 'reluctant to tamper with [the] enforcement scheme' embodied in the statute by extending remedies not specifically authorized by its text." *Great-West*, 534 U.S. at 209 (quoting *Russell*, 473 U.S. at 147) (alteration in original).

The general exclusion of monetary awards from ERISA's remedial scheme fits with the statute's overall emphasis on prospective remediation—to be accomplished where possible through internal review rather than through litigation. Indeed, a plan participant who is denied benefits by his ERISA plan is guaranteed a "full and fair review" by an "appropriate named fiduciary" without the need to pursue judicial remedies. ERISA § 503(2), 29 U.S.C. § 1133(2); 29 C.F.R. § 2560.503-1(h)(1). Because of the careful integration of Section 503, which provides for internal review, and Section 502, which provides for judicial review, the courts of appeals are in agreement that a plan participant *must* exhaust his remedies under the plan's procedures before bringing a

civil action for benefits under Section 502. *E.g.*, *Fallick v. Nationwide Mut. Ins. Co.*, 162 F.3d 410, 418 & n.4 (6th Cir. 1998) (citing cases); *see also* 29 C.F.R. § 2560.503-1(*l*) (implicitly recognizing the existence of an exhaustion requirement). And although ERISA provides a disincentive to litigate by favoring nonjudicial remedies and limiting the availability of court-imposed relief, the statute also furnishes an appropriate counterbalance to the risk of "underenforcement of beneficiaries' statutory rights" by permitting courts to award successful ERISA plaintiffs their attorney's fees. ERISA § 502(g), 29 U.S.C. § 1132(g); *Russell*, 473 U.S. at 147.

Thus, "upon close consideration of ERISA's interlocking, interrelated, and interdependent remedial scheme, which is in turn part of a comprehensive and reticulated statute," this Court has concluded that federal courts in ERISA actions may not award remedies not specifically authorized in the statute, such as consequential and exemplary damages. *Russell*, 473 U.S. at 146 (internal quotation marks omitted).

2. In *Pilot Life Insurance Co. v. Dedeaux*, 481 U.S. 41 (1987), a unanimous decision authored by Justice O'Connor, this Court announced the corollary to *Russell*'s limitation of federal expansion of ERISA remedies: States likewise may not disturb the careful balance struck by Congress by authorizing additional remedies for conduct actionable under ERISA. Such efforts to expand ERISA's remedial scope under state law are preempted by ERISA. *Pilot Life* controls this case and compels reversal of the Fifth Circuit's decision.

Pilot Life held preempted a state common law claim for "bad faith" denial of plan benefits. As in this case, plaintiff Dedeaux sought to import a state standard of reasonableness into the context of ERISA-governed benefits administration. When Pilot Life terminated his disability benefits under the terms of his ERISA plan, Dedeaux alleged that the termination was in "bad faith." *Id.* at 43. Rather than sue for the denied benefits under ERISA § 502(a), Dedeaux brought a tort

action under Mississippi law, seeking to recover compensatory and punitive damages. *Id.* at 43, 50.

This Court unanimously held that Dedeaux's claim was preempted by ERISA. Adopting the Solicitor General's suggestion, the Court held that the finely balanced nature of ERISA's civil enforcement scheme, which the Court had recognized in *Russell*, required that its status as the exclusive remedy for a benefits-administration decision be protected, by preemption if necessary. 481 U.S. at 53. In addition, in enacting ERISA, Congress had deliberately echoed the expansive preemption effected by Section 301 of the Labor-Management Relations Act, 29 U.S.C. § 185. That provision displaces all state-law claims predicated on contracts between unions and management, "even when the state action purport[s] to authorize a remedy unavailable under the federal provision." *Pilot Life*, 481 U.S. at 55. The Court in *Pilot Life* concluded that Congress had "modeled" Section 502(a)'s "pre-emptive force" on Section 301, and that Section 502(a) likewise preempts state-law claims that would supplement the remedies it provides. *Id.* at 54-55.

The Court noted in *Pilot Life* that Dedeaux's bad-faith claim for punitive damages amounted to an attempt to obtain state-law "remedies for the improper processing of a claim for benefits under an ERISA-regulated plan"—remedies "that Congress rejected in ERISA." Mindful of the potential disruption to Section 502(a)'s uniform enforcement scheme that a contrary holding would cause, this Court held his state-law claim preempted. 481 U.S. at 57.

That same day, this Court decided *Metropolitan Life Insurance Co. v. Taylor*, 481 U.S. 58 (1987)—also unanimous, also authored by Justice O'Connor. *Metropolitan Life* built upon *Pilot Life*'s holding by concluding that Section 502(a)'s preemptive force is so strong that any claim within its scope must be recharacterized as a federal claim—*i.e.*, one that can support removal jurisdiction. *Id.* at 65-66; *compare Fran-*

chise Tax Bd. v. Constr. Laborers Vacation Trust, 463 U.S. 1, 25-26 (1983) (defensive preemption under Section 514 does *not* confer removal jurisdiction). Thus, when plaintiff Taylor sued his employer and plan administrator in state court, alleging that they had wrongfully terminated his disability benefits, the tort and contract claims he alleged were "within the scope" of Section 502(a), and could be removed on that basis. *Metropolitan Life*, 481 U.S. at 62-63, 66.

The holdings in *Metropolitan Life* and in *Pilot Life* that the state-law claims could not proceed represented a straightforward application of well-settled preemption principles. ERISA's remedial provisions strike a balance between competing interests, facilitating the swift and inexpensive recovery of benefits while affording plan administrators a degree of certainty and predictability that allows them to hold down costs. *E.g.*, *Mertens*, 508 U.S. at 262-63; *Russell*, 473 U.S. at 146-47. That closely interwoven compromise would rapidly unravel if state law were permitted to undermine that certainty by imposing varying standards of care on insurers and authorizing large damage awards for any missteps. Thus, any state-law remedy that supplements or expands those that Congress included in Section 502(a) "pose[s] an obstacle to the purposes and objectives of Congress," even when—*especially* when—the state-law claim does not precisely overlap with the ERISA cause of action. *Pilot Life*, 481 U.S. at 52; *see Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Under ordinary conflict preemption principles, such a supplemental remedy is barred.

3. Because the application of these preemption principles follows naturally from this Court's conclusion that ERISA's remedial provision is exclusive and does not authorize the award of non-enumerated forms of relief, this Court has remained consistent in its exposition of the preemption framework under Section 502(a). The core holding of *Pilot Life* remains unchallenged by even a single dissenting vote to

date: the exclusivity of Section 502(a) prevents States from creating alternative rights of recovery based on conduct that could be challenged under ERISA.

This Court unanimously confirmed in *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133 (1990), that the remedies available under ERISA § 502(a) are the exclusive means of redressing ERISA-protected rights, and that plaintiffs cannot circumvent Section 502(a)'s exclusivity simply by demanding different remedies. There, as here, a plaintiff sued in state court under Texas law, seeking compensatory and punitive damages; he had been fired by his employer and alleged that the termination was calculated to prevent his pension rights from vesting. *Id.* at 135-36. The Texas Supreme Court thought that because the plaintiff was not seeking the recovery of benefits that Section 502(a)(1)(B) guarantees, his action could proceed under state law despite the preemptive force of Section 502(a). *Id.* at 136 (citing *McClendon v. Ingersoll-Rand Co.*, 779 S.W.2d 69, 71 n.3 (Tex. 1989)). This Court reversed, holding that because ERISA protects employees from such terminations—just as it protects plan beneficiaries' right to receive benefits according to the terms of the plan—any relief for a violation of an ERISA-protected right must come under Section 502(a). *Id.* at 144-45.

The cases holding that Section 502(a) preempts state-law causes of action seeking forms of relief unauthorized by ERISA are summed up in *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002). There, this Court considered an Illinois statute that gave participants in an employee benefit plan the right to submit precertification decisions to an independent review organization (IRO). All Members of the Court agreed that had the Illinois statute authorized a "new cause of action" or a "new form of ultimate relief," it would plainly have been controlled by *Pilot Life* and its progeny. *Id.* at 379; *see id.* at 394 (Thomas, J., dissenting). A majority of the Court held that the claim seeking the IRO appeal was not com-

pletely preempted, because the statute allowed no new form of judicial review or relief—the IRO's decisions would be enforced pursuant to Section 502(a), and "the relief ultimately available would still be what ERISA authorizes in a suit for benefits under [Section 502(a)(1)(B)]." *Rush Prudential*, 536 U.S. at 379-80. Four Members of the Court contended that even though the statute did not create an unauthorized form of judicially awarded relief, *Pilot Life*'s rule was nonetheless applicable because arbitration, which the dissenting Justices viewed as analogous to the IRO's binding determination, "constitutes an alternative remedy to litigation." *Id.* at 395 (Thomas, J., dissenting). The Court was thus unanimous in considering damages claims like Davila's preempted.

Pilot Life and *Metropolitan Life* expressly held, and *Ingersoll-Rand* and *Rush Prudential* confirm, that an action is within the scope of ERISA's remedial provision—and is therefore completely preempted—if it challenges conduct that could have been challenged in an ERISA action, but takes a form not authorized by ERISA, *i.e.*, it purports to authorize actions for relief not permitted by ERISA or based on conduct not actionable under ERISA. A state law "patently violates ERISA's policy of inducing employers to offer benefits by assuring a predictable set of liabilities" if, as the THCLA seeks to do in this case, the law "provide[s] a form of ultimate relief in a judicial forum that add[s] to the judicial remedies provided by ERISA." *Rush Prudential*, 536 U.S. at 379.

B. Davila's Challenge To Aetna's Interpretation Of The Monitronics Plan Is Preempted

Davila's claim, at bottom, is that Aetna failed to approve coverage for Vioxx. The complaint is somewhat ambiguous as to whether Davila contends that Aetna was required under the plan to pay for Vioxx or, alternatively, that Aetna was

required to pay for Vioxx regardless of the plan terms. Either way, however, his state-law claims are preempted by ERISA.

At times, Davila appears to assert that Vioxx was a covered medication. *See, e.g.*, Pet. App. 65a ("AEtna refused to provide Vioxx for relief of the pain caused by Juan Davila's arthritis his treating physician prescribed, *despite Vioxx being on the AEtna formulary*" (emphasis in original)). But if this is the basis of Davila's claims, his remedy lies under ERISA § 502(a)(1)(B), which authorizes a participant to sue in federal court "to recover benefits due to him under the terms of his plan." 29 U.S.C. § 1132(a)(1)(B). To be sure, it might be difficult to prevail on such a claim: Not only does the formulary make coverage for Vioxx conditional, but the Monitronics Plan expressly vests Aetna with discretion in the determination of coverage (J.A. 34-35) and, thus, Aetna's coverage determination would be reviewed with substantial deference. *See Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989). But as *Pilot Life* makes clear, the mere fact that state law may provide for more lenient standards, or additional remedies, does not authorize courts to ignore the comprehensive remedial scheme established under ERISA. 481 U.S. at 54 (cautioning that additional remedies would "completely undermine[]" ERISA).

At other times, Davila appears to assert that Aetna was obliged to cover Vioxx notwithstanding the terms of the Monitronics Plan. *See, e.g.*, Pet. App. 68a-69a ("AEtna failed to use ordinary care in . . . making health-care decisions regarding Juan Davila through its *adherence* to its prescription drug formulary policies" (emphasis added)). But if this is Davila's claim, it directly conflicts with ERISA § 502(a)(1)(B), which authorizes a participant to sue to "*enforce* his rights *under the terms of the plan*." 29 U.S.C. § 1132(a)(1)(B) (emphasis added). The express right to enforce the terms of the plan necessarily precludes any putative state right to alter, amend, or modify the terms of the plan, let

alone one to hold the plan's insurer liable for punitive damages merely for adhering faithfully to those terms. Davila's claims, which would require ignoring the plain language of the plan, are clearly precluded by *Pilot Life* and its progeny. *See, e.g.*, *Rush Prudential*, 536 U.S. at 379-80, 386 (confirming that challenges to plan design are completely preempted if they authorize a "form of ultimate relief" not allowed under ERISA).[11]

Accordingly, however characterized, Davila's THCLA claims fall within the scope of ERISA's remedial provision. Davila could have sought redress through the internal review procedures spelled out in the Secretary of Labor's regulations, or filed an action in federal court. Yet Davila opted instead to proceed with state-law claims seeking relief that is unavailable under ERISA for a supposed violation of an ERISA-protected right, just as the plaintiff in *Ingersoll-Rand* sought damages—rather than the available injunctive or "other appropriate equitable relief" available under Section 502(a)(3)—for an alleged termination motivated by a desire to avoid paying pension benefits. *See* 498 U.S. at 142-43; *see also Pilot Life*, 481 U.S. at 43-44, 52 (Dedeaux's damages claim was based on the "improper processing of a claim for benefits" and was therefore preempted, even though Dedeaux had styled it as a suit for tortious breach of contract). Therefore, under *Pilot Life* and its progeny, Davila's claims are completely preempted.

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[11] Indeed, had Aetna departed from the terms of coverage as Davila claims state law demands, it and Monitronics would have been subject to suit for a "violat[ion of] the terms of the plan." ERISA § 502(a)(3)(A); *see also id.* § 502(a)(3)(B)(ii). Plainly, "when compliance with both state and federal law is impossible," conflict preemption principles require that the state law yield under the Supremacy Clause. *E.g.*, *United States v. Locke*, 529 U.S. 89, 109 (2000) (citations and internal quotation marks omitted).

II. The Fifth Circuit Erred In Failing To Apply The Settled Rule Of *Pilot Life* And Its Progeny

Because *Pilot Life* and its progeny are directly on point, the question of preemption presented to the court of appeals was a straightforward one. Indeed, the court of appeals conceded that "*Pilot Life* . . . arguably supports CIGNA and Aetna's reading" of Section 502, although it characterized the basic principles of remedial exclusivity and conflict preemption discussed above as merely "expansive language." Pet. App. 19a. The Fifth Circuit justified disregarding this Court's holding in *Pilot Life* based on impressions it derived, incorrectly, from other ERISA cases.

Even were the Fifth Circuit not squarely precluded from reexamining this Court's precedents of its own volition,[12] the cases on which it premised its bobtailed reading of *Pilot Life*—*Pegram v. Herdrich*, 520 U.S. 211 (2000), and a series of cases construing ERISA § 514—do not justify its departure from precedent.[13] *Pegram* resolved a question of fiduciary liability—not preemption—applicable to treating physicians who are also HMO co-owners, and who consequently must engage in *both* medical treatment and coverage interpretation. An HMO that provides no medical services does

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[12] *See, e.g.*, *State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997); *Agostini v. Felton*, 521 U.S. 203 (1997); *Rodriguez de Quijas v. Shearson/Am. Express Inc.*, 490 U.S. 477, 484 (1989).

[13] The Fifth Circuit also invoked *Rush Prudential* as a basis for its assertion that "*Pilot Life* does not sweep so broadly" (Pet. App. 19a), but as discussed above, *Rush Prudential* in fact *reaffirms* that States may not create a "new cause of action under state law and authorize[] a new form of ultimate relief," particularly one that, like the punitive and consequential damages Davila seeks, "'Congress rejected in ERISA.'" *Rush Prudential*, 536 U.S. at 378, 379 (quoting *Pilot Life*, 481 U.S. at 54); *see supra* pp. 25-26; *see also* CIGNA Br. 10, 18-21.

not make "treatment decisions" that can be challenged under state law standards without regard to ERISA; it makes only coverage determinations, for which Section 502(a) provides the exclusive vehicle of judicial review. And because the THCLA claims conflict directly with the exclusivity of Section 502(a), there is no need to engage in the wholly distinct preemption analysis prescribed by Section 514.

A. State-Law Challenges To "Medical Necessity" Coverage Determinations Are Preempted By ERISA

The preemption doctrine developed in *Pilot Life* and its progeny is fully applicable to *any* state-law challenge to a coverage decision. It makes no difference whether that decision is based on an interpretation of a specific exclusion, a copayment requirement, or (as here) a "medical necessity" requirement that incorporates both financial and medical criteria. The court of appeals, however, concluded that a medical necessity determination is a so-called "mixed eligibility and treatment decision" that is not subject to ERISA's exclusive remedial scheme. Pet. App. 13a. This was a clear misreading of this Court's decision in *Pegram*.

1. *Pegram* involved an action under ERISA for breach of fiduciary duty. The plaintiff, Herdrich, was a participant in a group-model HMO, in which the physicians owned the HMO *and* provided medical services to HMO participants.[14] Unlike a network-model HMO (such as the one at issue in this case), the HMO in *Pegram* did not reimburse doctors for providing covered services; rather, the HMO compensated its physician co-owners according to the quantity of services they provided through the HMO each year. *See* 530 U.S. at 216 n.3; Ann Barry Flood et al., *The Promise and Pitfalls of Explicitly Rewarding Physicians Based on Patient Insurance*,

[14] *See supra* note 1 (discussing different HMO models).

23 J. AMBULATORY CARE MGMT. 55, 58, 62 (2000) (detailed study of the HMO that was the petitioner in *Pegram*).

Herdrich alleged that the physician (and HMO co-owner) who examined her discovered an inflamed mass in her abdomen, but did not order an immediate ultrasound. Instead, Herdrich's doctor directed her to wait the eight days necessary for the ultrasound to be provided by a facility owned by the HMO. During that time, Herdrich's appendix ruptured. She sued, asserting that the HMO had a fiduciary duty to make determinations in the best interests of the patient, and that this duty was automatically breached by the HMO's organization along lines that rationed care on the basis of cost-saving principles. 530 U.S. at 216. This Court rejected that claim.

The *Pegram* Court articulated a tripartite framework for evaluating ERISA claims alleging breach of fiduciary duties by HMOs that act through their physician owners. "[P]ure 'eligibility decisions' turn on the plan's coverage of a particular condition or medical procedure for its treatment"; "'[t]reatment decisions' . . . are choices about how to go about diagnosing and treating a patient's condition"; and "mixed eligibility and treatment decisions," including "medical necessity determinations," have aspects of both. 530 U.S. at 228-29. The holding of *Pegram* is that "Congress did not intend [the HMO at issue] or any other HMO to be treated as a fiduciary to the extent that it makes mixed eligibility decisions acting through its physicians." *Id.* at 231.

2. The court of appeals recognized, but failed to appreciate the significance of, the crucial distinction between this case and *Pegram*. The court acknowledged that "Herdrich claimed that her doctor made the erroneous medical decision," whereas Davila claimed that the HMO (Aetna) did. Pet. App. 14a. The court said, however, that "*Pegram*'s reasoning indicates that this distinction is immaterial to the § 502(a)(2) analysis." *Id.* Aside from the fact that this is not

a Section 502(a)(2) case alleging breach of fiduciary duty (since Davila has refused even to attempt to plead a claim under ERISA),[15] Aetna *does not make* medical decisions under the Monitronics Plan. *See* J.A. 106 ("Participating Physicians maintain the physician-patient relationship with Members and are solely responsible to Member for all Medical Services which are rendered by Participating Physicians" (boldface omitted)).

Unlike physician owners of a group-model HMO, administrators of network-model HMOs do not make treatment decisions. This Court recognized as much in *Pegram*: "Traditional trustees administer a medical trust by paying out money to buy medical care, whereas physicians making mixed eligibility decisions consume the money as well. *Private trustees do not make treatment judgments*, whereas treatment judgments are what physicians reaching mixed decisions do make, by definition." 530 U.S. at 231-32 (emphasis added). The "mixed questions" referred to in *Pegram* simply do not exist outside the context of the physician-

[15] The court below said that Aetna was "not acting as [a] plan fiduciar[y] when denying [Davila] medical treatment." Pet. App. 12a. There are two problems with this statement. First, Aetna did not deny Davila any medical treatment; it simply determined that Vioxx was not a covered benefit that it could pay for under the plan. Davila remained free to have his Vioxx prescription filled or to challenge Aetna's coverage decision. Second, it makes no difference for purposes of complete preemption whether or not Aetna was acting in a fiduciary capacity. Section 502(a) provides the exclusive remedies available for subscriber grievances arising out of plan administration, against both plan fiduciaries *and* non-fiduciaries. Indeed, one provision (Section 502(a)(2)) applies only to breaches of fiduciary duty (*see* ERISA § 409, 29 U.S.C. § 1109), indicating that the remainder are available to the identified plaintiffs regardless of the fiduciary status of the defendant. *E.g.*, SACHER, *supra*, at 901.

owned HMO at issue in that case, or a staff-model HMO, because network-model HMOs do not "act[] through their physicians." *Id.* at 231; *see id.* at 237 ("We hold that mixed eligibility decisions *by HMO physicians* are not fiduciary decisions under ERISA"); *accord* CIGNA Br. at 31-32. *Compare* J.A. 106 ("No Participating Provider . . . is an agent or employee of [Aetna]" (boldface omitted)). As a result, *Pegram* has nothing to do with this case.[16]

Although standards of care or treatment may enter into the "medical necessity" determination, they do so in aid of a pure coverage judgment—*i.e.*, must the plan pay for this proposed treatment?—and the ultimate decision to approve or deny coverage based on that plan term thus remains one of plan administration. In this case, it cannot be disputed that Vioxx can be approved only conditionally under the Monitronics Plan formulary, and it is likewise plain that no precondition to approval was met. Aetna's decision that Vioxx was not "medically necessary" thus was not a treatment decision, but rather reflected the terms of the plan itself. And the only person who *treated* Davila's condition by recommending that Davila try Naprosyn was his attending physician.

Because the structure of a physician-owned HMO requires "the physicians through whom [such] HMOs act" to make mixed eligibility and treatment decisions, patients can—as Herdrich in fact did (*see* 530 U.S. at 217)—obtain

[16] The Court stated in *Pegram* that it was "not in a position to derive a sound legal principle to differentiate [the group model HMO at issue] from other HMOs." 530 U.S. at 222. This statement was made in the context of fiduciary "decisions made by all HMOs *acting through their owner or employee physicians*." *Id.* (emphasis added). Aetna's HMO products, including the services it provides the Monitronics Plan, are not owned by and do not employ treating physicians, and thus there is a sound—indeed, dispositive—basis of distinction.

adequate relief for deficient care through traditional medical malpractice actions against the *physicians*. Of course, medical malpractice actions logically cannot be available against HMOs that do not provide medical services, or against physician-owned HMOs in States that do not subject managed care entities to the same level of state-law regulation as the individual physician owners. But, the Court noted, "we have seen enough to know that ERISA was not enacted out of concern that physicians were too poor to be sued, or in order to federalize *malpractice* litigation . . . for any other reason." *Id.* at 236 (emphasis added). ERISA federalizes only *benefits* litigation, and federalizes it completely, as *Pilot Life* established.

3. *Metropolitan Life* confirms that ERISA provides the exclusive means of challenging a benefits decision by an insurer that provides no treatment, even if the benefits decision includes some medical criteria. In that case, the employee (Taylor) had been found medically able to work and his disability insurance had therefore been terminated. 481 U.S. at 60-61. Despite the medical component of the insurer's decision (*see Taylor v. Gen. Motors Corp.*, 763 F.2d 216, 217-18 (6th Cir. 1985)), this Court recognized that Taylor's claims challenged benefits administration and, therefore, were maintainable under ERISA § 502(a) or not at all. 481 U.S. at 62-63 (characterizing Taylor's action as "a suit by a beneficiary to recover benefits from a covered plan" that was preempted by the "exclusive federal cause of action for resolution of such disputes"). The court of appeals' decision in this case is flatly irreconcilable with the holding of *Metropolitan Life*.

Indeed, just last Term this Court recognized in an analogous ERISA-determination context that although plan documents may incorporate certain medical concepts as eligibility criteria, the award of benefits under those plan documents is nonetheless a question of benefits administration rather than medical judgment. The dispute in *Black & Decker Disability*

Plan v. Nord, 123 S. Ct. 1965 (2003), concerned the award of benefits under a disability-insurance plan, under which the key eligibility determination was whether, "based on suitable medical evidence" and the employee's job history, the employee was medically able to continue in his regular occupation. *Id.* at 1967. The unanimous *Nord* opinion aptly explains the importance of treating these quasi-medical determinations as only one element in an insurer's determination that benefits are or are not authorized. In deciding how challenges to such decisions should be reviewed, this Court noted that while the opinion of a physician is one element—not *per se* entitled to any "special weight"—in the decision, the judgment "'is likely to turn,' in large part, 'on the interpretation of terms in the plan at issue.'" *Id.* at 1971 (quoting *Firestone Tire*, 489 U.S. at 115). *Nord* conclusively establishes that medical necessity determinations under an ERISA plan concern benefits administration, not medical treatment.

Thus, outside the unique context presented in *Pegram*, in which HMO co-owners provided medical treatment, that case's discussion of mixed eligibility and treatment decisions has no relevance to ERISA preemption. Where the treating physician's role is kept *separate* from benefits administration, the complete preemption doctrine has *no* effect on a plan beneficiary's ability to pursue a state-law remedy against his physician based on treatment, and ERISA creates no risk that malpractice litigation will be unnecessarily "federalize[d]." As the Solicitor General has explained, "[t]he better reading of *Pegram* . . . is that it addresses only mixed decisions made by *treating* physicians." Brief for the United States as *Amicus Curiae* at 8, *Rush Prudential HMO, Inc. v. Moran*, No. 00-1021 (Nov. 7, 2001). Indeed, any other reading of *Pegram* would contravene "the background . . . provisions of ERISA itself and longstanding Labor Department regulations." *Id.* at 9. Properly understood, *Pegram* does not disturb the core holding of *Pilot Life* and its progeny: ERISA continues to provide the exclusive means of challenging a

non-treating claims administrator's interpretation of the plan and completely preempts all alternative remedies, even if the plan incorporates a criterion such as "medical necessity."

Several courts of appeals have recognized that *Pegram* does not alter the preemption analysis of *Pilot Life*. The Third Circuit has stated its conclusion most plainly: "[T]he Court's holding that a 'mixed' determination made by a physician owner does not subject an HMO to liability for breach of fiduciary duty does not translate to, or govern in, the preemption context." *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 450 (3d Cir. 2003).[17] The Third Circuit went on to hold preempted a state-law medical-negligence claim challenging an insurer's decision that had "aspects of treatment and coverage." Applying a "medical necessity" requirement substantially identical to the Monitronics Plan's, Aetna had allegedly denied coverage for a specialized tracheostomy tube. Although in reaching that decision "Aetna necessarily had to exercise some medical judgment," the Third Circuit held that the determination nonetheless "could only have [been] an eligibility, not a treatment, decision," because Aetna did not itself provide the medical services. *Id.* at 448-49. Thus, applying both *Pegram* and its own, related precedent, the Third Circuit concluded that despite the aspects of diagnosis bound up with the plan determination, the decision was an eligibility determination and could be challenged under ERISA or not at all. *Accord, e.g.*, *Cicio v. Doe*, 321 F.3d 83, 109 (2d Cir. 2003) (Calabresi, J., dissenting in part) ("If this is not a paradigmatic suit to remedy the violation of rights under the terms of the plan, I don't know what is"), *petition for cert. filed*, No. 03-69 (docketed July 14, 2003).[18] Expanding *Pegram*'s "mixed eligibility and treatment decision" formulation outside the context of physician-owned HMOs would completely undo *Pilot Life*, because virtually *any* determination by a health or disability plan insurer can be characterized as a mixed question.

[17] The Third Circuit spoke with particular authority in this regard, because *Pegram*'s tripartite framework consciously echoed the analysis in an earlier Third Circuit decision. *Pegram*, 530 U.S. at 228 (citing *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350, 361 (3d Cir. 1995)). Although *Dukes* inaccurately blurred the distinction between HMOs' precertification of benefits and doctors' prescription of treatment, this Court recognized in *Pegram*, and the Third Circuit agreed in *DiFelice*, that that distinction blurs into a "mixed eligibility and treatment decision" *only* when the doctor works directly for or owns the HMO.

B. Recent Decisions Construing ERISA § 514 Do Not Alter The *Pilot Life* Analysis

The Fifth Circuit's determination to read *Pilot Life* narrowly may also have been influenced by its analysis, in the consolidated opinion, of the entirely distinct concept of defensive preemption under ERISA § 514, 29 U.S.C. § 1144, which under then-existing circuit precedent was deemed to be a component of the complete-preemption analysis under ERISA § 502(a). However, as the Fifth Circuit has since recognized in another case, the displacement of supplemental state-law remedies follows directly from principles of con-

[18] Several other circuits have likewise recognized that medical necessity determinations are benefits decisions, not treatment decisions, and that state-law tort challenges to those determinations are preempted under *Pilot Life*. *See, e.g.*, *Marks v. Watters*, 322 F.3d 316, 325-27 (4th Cir. 2003); *Hotz v. Blue Cross & Blue Shield of Mass.*, 292 F.3d 57, 60 (1st Cir. 2002) (reaffirming *Danca v. Private Health Care Sys.*, 185 F.3d 1, 5-6 (1st Cir. 1999)). A few other circuits have misread *Pegram* as the court below did. *See, e.g.*, *Land v. CIGNA Healthcare of Fla.*, 339 F.3d 1286, 1290-93 & n.5 (11th Cir. 2003), *petition for cert. filed*, No. 03-649 (docketed Oct. 30, 2003); *Cicio*, 321 F.3d at 102.

flict preemption.[19] Thus, the form of preemption for which *Pilot Life* and *Metropolitan Life* stand—"complete preemption"[20]—does not turn on interpretation of ERISA's broad defensive preemption clause, and *Pilot Life*'s core holding cannot be constricted based on augury of the signals allegedly sent by this Court's decisions interpreting Section 514.

ERISA § 514 preempts any aspect of state law that "relate[s] to" an ERISA plan. As this Court has noted, if that provision were applied literally, "then for all practical purposes pre-emption would never run its course." *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.* ("*Travelers*"), 514 U.S. 645, 655 (1995). Accordingly, a number of this Court's recent decisions—including the so-called "trilogy" of *Travelers*; *California Division of Labor Standards Enforcement v. Dillingham Construction, N.A.*, 519 U.S. 316 (1997); and *De Buono v. NYSA-ILA Medical & Clinical Services Fund*, 520 U.S. 806 (1997)—have sought to give some definition to the outer boundary of defensive preemption. However, as Davila himself notes, "section 502(a) complete preemption is very different from section 514's 'relates to' preemption." Br. in Opp. 1 n.1.

In cases following *Pilot Life* and *Metropolitan Life*, therefore, this Court has appropriately separated the com-

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[19] Fifth Circuit precedent formerly dictated that in order to support removal under *Metropolitan Life*, a claim must be both completely preempted by Section 502(a) *and* defensively preempted by Section 514. *See, e.g., Hartle v. Packard Elec.*, 877 F.2d 354, 355 (5th Cir. 1989). The Fifth Circuit has since overruled those precedents. *Arana v. Ochsner Health Plan*, 338 F.3d 433, 440 (5th Cir. 2003) (en banc), *petition for cert. filed*, No. 03-542 (docketed Oct. 10, 2003).

[20] "Congress may so completely pre-empt a particular area that any civil complaint raising this select group of claims is necessarily federal in character." *Metropolitan Life*, 481 U.S. 63.

plete-preemption and defensive-preemption inquiries. *See, e.g., Ingersoll-Rand*, 498 U.S. at 142 ("*Even if there were no express pre-emption in this case*, the Texas cause of action would be pre-empted because it conflicts directly with an ERISA cause of action" (emphasis added)); *accord Rush Prudential*, 536 U.S. at 377 (anticipating that a saved "state insurance regulation los[es] out if it allows plan participants 'to obtain remedies . . . that Congress rejected in ERISA'" (quoting *Pilot Life*, 481 U.S. at 54) (alteration in original)).[21]

This Court's cases construing other ERISA provisions have likewise concluded that a direct conflict with a specific provision of ERISA compels a finding of preemption and does not require resort to the defensive-preemption clause. Thus, for example, in *Boggs v. Boggs*, 520 U.S. 833 (1997), this Court held preempted state statutes that conflicted directly with individual provisions of ERISA, and expressly discounted the need to analyze the preemption claim under the more general rubric of Section 514. *Id.* at 841 (holding that because state community property law conflicts with ERISA's "anti-alienation" provision, application of conflict preemption principles "suffices to resolve the case," and the Court "need not inquire whether [Section 514] provides further and additional support for the pre-emption claim").

For this reason, cases construing ERISA's defensive-preemption provision relatively broadly or relatively nar-

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[21] The propriety of separate analysis of the two provisions is confirmed by cases construing other defensive-preemption provisions. *See Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000) ("[T]he saving clause (like the express pre-emption provision) does not bar the ordinary working of conflict pre-emption principles"); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287-89 (1995) (the inclusion of an express preemption clause does not foreclose the preemption of additional, directly conflicting state laws).

rowly are not instructive in applying the conflict-preemption principles that Section 502(a) invokes. Congress wrote Section 514 so broadly that it may plausibly have meant to delegate to this Court the authority to make relatively fine judgments based on the policy of ERISA and the competing state interests at stake. *Cf. Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 687-88 (1978) (noting that the Sherman Act has language so broad "that it cannot mean what it says," and explaining that Congress "expected the courts to give shape to the statute s broad mandate by drawing on common-law tradition"). In Section 502(a), by contrast, Congress spoke with sufficient clarity to overcome the presumptions that have motivated some of this Court's recent retrenchments in ERISA-preemption cases. *E.g.*, *Ingersoll-Rand*, 498 U.S. at 144 ("It is clear to us that the exclusive remedy provided by § 502(a) is precisely the kind of special feature that warrants pre-emption in this case" (internal quotation marks and alterations omitted)); *see also Metropolitan Life*, 481 U.S. at 64, 66 (referring to the "explicit direction from Congress" and observing that "[n]o more specific reference to the *Avco* rule [of exclusive remedies and complete pre-emption of alternatives] can be expected").[22]

III. This Court Should Not Overrule The *Pilot Life* Line Of Cases

As demonstrated above, Davila's claims are foreclosed by the core holdings of *Pilot Life* and its kin—that ERISA's remedial provision is exclusive; that that exclusivity gives rise to preemption of any state cause of action within its scope; and that preemption is so complete as to confer re-

[22] And even in its recent Section 514 cases, this Court "ha[s] not hesitated" to find an "area[] of traditional state regulation" to be "pre-empted when it conflicts with ERISA or relates to ERISA plans." *Egelhoff v. Egelhoff*, 532 U.S. 141, 151 (2001).

moval jurisdiction. Having adhered consistently to those principles over the nearly two decades since *Russell* was decided, this Court should decline any request that it reexamine these settled precedents.

A. Overruling *Pilot Life* Would Undermine The Settled Expectations Of Insurers, Employers, And Participants

A retreat from *Pilot Life* would allow the plaintiffs' bar to mount a frontal assault on the concept of managed care, an assault that both Congress and this Court have declined to countenance. Using state laws such as the THCLA, plan participants would seek benefits that they neither contracted nor paid for, driving up costs for insurers and employers, and ultimately for employees. Such a liability regime is wholly inconsistent with ERISA as this Court has consistently construed it, and there is no basis in law or logic to depart from that longstanding construction.

1. The principle of *stare decisis* bears "special force in the area of statutory interpretation." *Patterson v. McLean Credit Union*, 491 U.S. 164, 172 (1989). Not only does the general value of certainty and predictability in application of the law counsel against overruling a statutory precedent; so too does a sound conception of the relationship between the judicial and the legislative power, because Congress retains the ability to overrule any construction that it deems incorrect as a matter of law or inadvisable as a matter of policy. *Id.* Therefore, in order even to ask this Court to part company with the *Pilot Life* line of cases, Davila and his *amici* must show, in addition to the "special justification" required of all who seek a departure from *stare decisis* (*Arizona v. Rumsey*, 467 U.S. 203, 212 (1984)), an additional basis for overcoming the "presumption of adherence" to statutory-interpretation precedents. *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 736 (1977). This is a showing they cannot make.

Moreover, the circumstances of this case fail to demonstrate the "necessity and propriety" (*Patterson*, 491 U.S. at 172) of overruling a statutory interpretation that has been consistently adhered to—and without dissent—for almost two decades. *Cf. Illinois Brick*, 431 U.S. at 737 (adhering to a construction "joined by eight Justices without dissent only a few years ago"). None of the indicia of legislative intent on which this Court relied in *Pilot Life* has been discredited or superseded. No significant change has been made in Section 502(a) that would justify a reexamination of the core holding of several past decisions consistently interpreting that statute. Indeed, Congress has enacted sundry amendments to Section 502(a) since *Pilot Life* and *Metropolitan Life* were decided, but has made no change that would suggest disapproval of the notion of exclusivity or of the doctrine of complete preemption.[23] And this Court's cases have consistently adhered to *Pilot Life* and its progeny; with the passage of time and the ratification of subsequent—unanimous—decisions, any assertion that the *Pilot Life* family of cases is aberrational becomes all the more implausible. Indeed, this Court generally reaffirmed and expanded upon the complete-preemption

[23] To the contrary: even "patients' rights" legislation that Congress has considered (but failed to pass) in recent years has adhered to the principle that any damages remedy for eligibility determinations under an ERISA plan should be exclusively *federal*. *See* H.R. 2563, § 402 (2001) (passed by the House). Although some Members of Congress have proposed legislation to undo the exclusivity recognized in *Pilot Life*, no such legislation has ever been enacted, and even those proposals have recognized that any overruling of *Pilot Life*'s preemption holding would have to be accompanied by limitations on state-law damages and continued adherence to ERISA's exhaustion requirements, to avoid a radical increase in health care costs. *See* S. 1052, § 402(b) (2001).

analysis in *Metropolitan Life* just last Term. *Beneficial Nat'l Bank v. Anderson*, 123 S. Ct. 2058, 2062-63 (2003).[24]

2. This Court should be particularly hesitant to overrule wholesale a line of cases in which American employers, employees, and employee benefit plans have invested such considerable reliance. The complexity of the compromise that produced Section 502(a) bespeaks the considerable importance of maintaining that compromise. In selecting the available remedies and foreclosing others, Congress struck a balance between "the primary [ERISA] goal of benefitting employees and the subsidiary goal of containing [benefit] costs." *Mertens*, 508 U.S. at 262-63 (internal quotation marks omitted). Indeed, employers (including the federal government) have embraced the HMO model precisely because that model confines the managed care entity's duties to plan administration, subjecting it to ERISA's "*predictable* set of liabilities, under uniform standards of primary conduct and a uniform regime of ultimate remedial orders and awards when a violation has occurred." *Rush Prudential*, 536 U.S. at 379 (emphasis added); *see* AAHP-HIAA Amicus Br. 16-17. To undo the balance struck in 1974 and consistently adhered to by this Court would cause a significant shock to the Nation's system of employee benefits and would require employees to bear increased premiums, decreased coverage, or both. *See* U.S. Chamber Amicus Br. 24-26.

The predictability of the ERISA remedial framework has been relied upon to price tens of thousands of employee benefit contracts since *Pilot Life* was decided. Insurers and

[24] Even if one does not accept as an original matter that complete preemption is sufficient to confer removal jurisdiction, one may fairly agree that Congress expressly endorsed such a result in the ERISA context by adopting language strikingly parallel to the LMRA's. *Beneficial*, 123 S. Ct. at 2067 n.1 (2003) (Scalia, J., dissenting).

administrators of ERISA benefit plans have been cognizant of their responsibilities and their liabilities under the governing law, and have set their premiums and fees accordingly. For this Court now to allow the imposition of state-law standards that would override the plan terms would completely undo those actuarial pricing decisions. That course would simply confer a windfall on plaintiffs who never had to pay the higher costs associated with a fee-for-service plan (and would impose additional costs on future participants). At a time when medical costs are already high, affirmance of the decision below would deal a severe blow to the American economy.

The current system has not proved unworkable or judicially unmanageable. Indeed, the very prevalence of managed care strategies strongly suggests that the cost-containment strategies that this Court has identified as HMOs' *raison d'être* have succeeded in lowering premiums while maintaining an acceptable quality of benefits. This Court should not now decree an end to that widely adopted model of health coverage.

B. Overruling *Pilot Life* Is Not Necessary To Protect Participants Or Plan Benefits

That ERISA forecloses one crude means of regulating health plans—tort actions for money damages—certainly does not mean that health care consumers and state regulators enjoy no meaningful influence over the appropriate levels of medical care. To the contrary, plan members, employers, and state governments all retain substantive and valuable roles both in specifying the plan language that sets out these medical and non-medical criteria to be used in the HMO's coverage decision, and in regulating the application of that plan language.

1. Plan members and employers, for example, can use their bargaining or purchasing power to secure more gener-

ous coverage provisions, which increase the likelihood that care will be provided and, accordingly, increase premiums by a certain amount (depending on the size of the risk pool in which the ERISA plan participates). And medical professionals may refuse to participate in any particular HMO whose benefit plans depart too often from what treating physicians, exercising their Hippocratic obligations, see as appropriate medical treatment. Because HMOs' ability to offer cost savings turns in part on their relationship with in-network providers, the doctors have leverage as well.

In addition to encouraging market-based solutions, Congress has required health benefit plans to cover certain services that, in Congress's judgment, should not be subject to contractual exclusions. *See, e.g.*, Women's Health and Cancer Rights Act of 1998, Pub. L. No. 105-277, § 902, 112 Stat. 2681, 2681-436 to -437 (codified at ERISA § 713, 29 U.S.C. § 1185b); Newborns' and Mothers' Health Protection Act of 1996, Pub. L. No. 104-204, § 603, 110 Stat. 2874, 2935-28 (codified at ERISA § 711, 29 U.S.C. § 1185). In adding these mandated-benefits provisions to ERISA (while leaving employers otherwise free to design their own plan terms, *see Lockheed Corp. v. Spink*, 517 U.S. 882, 887 (1996)), Congress has recognized that the rights of action provided by Section 502(a) are adequate to enforce the required substantive elements of benefit plans.

Significantly, state regulation also may play a constructive role without tampering with ERISA's exclusive remedies: this Court has recognized that States may permissibly regulate the substantive terms of insurance plans by requiring, for example, that all health insurance coverage offered within a State include a certain minimum set of covered benefits. *E.g.*, *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 746 (1985) (upholding as not preempted a state statute requiring health plans to include coverage for mental health, and stating, "If a state law 'regulates insurance,' as

mandated-benefit laws do, it is not pre-empted"). So long as the regulation is "specifically directed toward" insurance companies and "substantially affect[s] the risk pooling arrangement between the insurer and the insured," it is saved from preemption under Section 514(b)(2)(A)'s insurance saving clause. *Kentucky Ass'n of Health Plans v. Miller*, 123 S. Ct. 1471, 1479 (2003).[25]

This Court has already given effect to one of the most significant forms of state regulation of insurers' eligibility determinations: the independent review organization. Recently in *Rush Prudential*, this Court held that Sections 502 and 514 do not preclude States from requiring HMOs to submit their benefit-eligibility determinations based on medical necessity to an independent review organization, at the claimant's election. The IRO procedure does not create any additional right to recovery of money damages; instead, it allows the independent reviewer rather than the HMO to have the final say as to "what is 'medically necessary' under [the plan] contract." *Rush Prudential*, 536 U.S. at 380. If necessary, a beneficiary can sue under ERISA to enforce

[25] Self-funded ERISA plans cannot be subjected to state mandated-benefits laws, because they are excluded from the set of saved state insurance regulations by Section 514's "deemer clause," 29 U.S.C. § 1144(b)(2)(B). *See, e.g.*, *Metropolitan Life v. Massachusetts*, 471 U.S. at 747 ("We are aware that our decision results in a distinction between insured and uninsured plans, leaving the former open to indirect regulation while the latter are not. By so doing we merely give life to a distinction created by Congress in the 'deemer clause,' a distinction Congress is aware of and one it has chosen not to alter"); *FMC Corp. v. Holliday*, 498 U.S. 52, 61 (1990) (explaining that self-funded plans are covered by the deemer clause exception). Of course, self-funded plans likewise cannot be subjected to alternative state-law remedies, because ERISA § 502(a)'s independent form of conflict preemption affects both self-funded and independently insured ERISA plans.

compliance with the IRO requirement or, once the IRO rules on the claim for coverage, to recover the benefits to which the IRO finds him entitled. *Id.* at 380 & n.10; *see also* U.S. Chamber Amicus Br. 20-21 (citing state IRO laws).

The Secretary of Labor, in regulations implementing Section 503's internal-appeal requirement, has expressly sanctioned these IRO procedures and deemed them consistent with ERISA, so long as they remain both independent and voluntary (*i.e.*, at the beneficiary's election). *See* 29 C.F.R. § 2560.503-1(k)(2). Texas was one of the first States to implement an IRO law, and the Monitronics Plan incorporates IRO review. J.A. 94-95. Consistently with the terms of the plan, Aetna advised Dr. Lopez that Davila could invoke his right to IRO review if he were dissatisfied with the denial of immediate coverage for Vioxx (Pet. App. 81a), but Davila states in his complaint that he did not do so. *Id.* at 69a-70a. And even had an IRO reversed Aetna's decision that Vioxx had not yet been shown to be covered in Davila's case, Davila would still have been unable to sue for the compensatory and punitive damages that he now demands: A permissible IRO provision "does not enlarge the claim beyond the benefits available in any action brought under [Section 502(a)]." *Rush Prudential*, 536 U.S. at 380. By contrast, Davila seeks to assert a "new cause of action under state law" and to recover "a new form of ultimate relief"—claims that are "patently" preempted. *Id.* at 379.

Where the States are foreclosed from regulating is in prescribing additional *remedies* for breach of these state-mandated obligations. *Rush Prudential*'s focus on the non-remedial nature of Illinois's IRO law makes plain this core area of *Pilot Life* preemption. Likewise, in *UNUM Life Insurance Co. of America v. Ward*, 526 U.S. 358 (1999), this Court distinguished between a permissible state law that provides the "relevant rule of decision" in a suit under ERISA § 502(a)(1)(B) to recover benefits due, and an impermissible

state cause of action that supplements the exclusive remedial scheme of ERISA § 502(a). *Id.* at 377. Thus, while this Court has upheld state laws imposing new standards on insurance policies offered through employee benefit plans—noting that the attendant "disuniformities . . . are the inevitable result of the congressional decision to 'save' local insurance regulation," *id.* at 376; *Metropolitan Life v. Massachusetts*, 471 U.S. at 747—it has foreclosed state attempts to supplement their unique standards with new causes of action and forms of relief that diverge from those available nationwide under ERISA.

Saving substantive risk-related regulation, but foreclosing supplemental remedies, fosters predictability and reduces the cost of benefits administration—two important goals of ERISA. Allowing the mandatory addition of terms to insurance contracts leaves the insurer—or the ERISA plan—free to perform its actuarial calculations based on the mandated terms, to negotiate prices with those calculations in mind, and to walk away from an inadequate bargain. The insurer may also contract with employers to secure the appropriate standard by which its decisions interpreting the mandatory language will be reviewed. *Firestone Tire*, 489 U.S. at 115. By contrast, allowing the enforcement of state-law standards through state-law remedies—potentially including consequential and punitive damages in significant and unpredictable amounts—would effectively undo insurers' past pricing decisions and introduce a significant element of uncertainty into future actuarial calculations—an element of uncertainty that will likely produce much higher prices than the mere addition of the mandated benefit to the plan terms would cause.

2. Although employee welfare benefit plans offer varying types of benefits, from disability insurance to health coverage, and each of these plans imposes its own eligibility criteria, they are all subject to the same, nationally uniform set of remedies set out in ERISA. The statute leaves it to the

individual plan to tailor the eligibility criteria to fit the benefit at issue, subject to permissible state-law regulation of the benefits that a qualified insurer may or must offer. ERISA prescribes only the uniform remedy. It is precisely that uniformity that *Pilot Life* secured; the Fifth Circuit overlooked; and Davila's THCLA claims threaten to undermine. For this reason, even those who disagree with this Court's reading of ERISA's remedial provisions in cases like *Mertens*, and who sympathize with results like those reached by the court below, recognize that "opportunistic attacks on preemption" are not the appropriate means of achieving those results: disrupting the essential uniformity of Section 502(a)—even if misconstrued—would "serve mainly to complicate ERISA and to create anomalous results" for both beneficiaries and providers. *Cicio*, 321 F.3d at 107 (Calabresi, J., dissenting in part); *see also DiFelice*, 346 F.3d at 465-66 (Becker, J., concurring).[26] Even these critics recognize that their policy concerns should be addressed within ERISA's uniform federal framework. *See* U.S. Chamber Br. at 24.

That uniform framework would be undone, and the predictability and certainty secured by the *Pilot Life* line of decisions would be obliterated, by affirmance of the decision be-

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[26] Indeed, even the academic criticism cited in the *DiFelice* concurrence and the *Cicio* dissent directs little firepower in the direction of the core holding of *Pilot Life*, *i.e.*, that Section 502(a) is exclusive and preempts any disruption of that exclusivity. Rather, the law review articles cited by Judges Becker and Calabresi take aim primarily at this Court's decisions in *Mertens* and *Great-West*, in which this Court rejected plaintiffs' attempts to obtain monetary awards under the rubric of equitable relief. This case does not present a vehicle to reexamine those cases—not only has Davila not sought equitable relief under ERISA, he has sought a remedy, punitive damages, that even the critics of *Mertens* and *Great-West* do not think ERISA can be read to authorize—and no party has requested that this Court do so.

low. Because HMOs are *required* to have a medical professional available to review the denial of benefits based on medical necessity (*see* 29 C.F.R. § 2560.503-1(h)(3)(iii)), *any* such claim against an HMO can be characterized as based on a "mixed decision," as the Fifth Circuit construed that term. The inevitable, and immediate, consequence would be an increase in healthcare costs or a decrease in available coverage, and quite probably both. *See* U.S. Chamber Amicus Br. at 24-26. In the absence of any compelling legal or logical reason to depart from *Pilot Life*, this Court should refrain from delivering such an unwarranted shock to the American economy. Even if opponents of *Pilot Life* could show some policy reason for imposing greater liability on HMOs under state law—and Aetna submits they cannot—they should address that showing to Congress, not to this Court.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

JOHN B. SHELY
KENDALL M. GRAY
ANDREWS & KURTH LLP
600 Travis, Suite 4200
Houston, Texas 77002
(713) 220-4200

ROY T. ENGLERT, JR.
ROBBINS, RUSSELL, ENGLERT, ORSECK & UNTEREINER LLP
1801 K Street, N.W.
Washington, D.C. 20006
(202) 775-4500

MIGUEL A. ESTRADA
Counsel of Record
MARK A. PERRY
WILLIAM M. JAY
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036-5306
(202) 955-8500

J. EDWARD NEUGEBAUER
AETNA HEALTH INC.
980 Jolly Road (U19A)
Blue Bell, PA 19422
(215) 775-5939

Counsel for Petitioner

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UNITED STATES CODE

TITLE 29—LABOR

CHAPTER 18—EMPLOYEE RETIREMENT SECURITY PROGRAM

SUBCHAPTER 1—PROTECTION OF EMPLOYEE BENEFIT RIGHTS

SUBTITLE B—REGULATORY PROVISIONS

* * * * *

§ 1133. Claims Procedure

In accordance with regulations of the Secretary, every employee benefit plan shall—

(1) provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant, and

(2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.

CODE OF FEDERAL REGULATIONS

TITLE 29—LABOR

CHAPTER XXV—EMPLOYEE BENEFITS SECURITY ADMINISTRATION, DEPARTMENT OF LABOR

PART 2560—RULES AND REGULATIONS FOR ADMINISTRATION AND ENFORCEMENT—Table of Contents

§ 2560.503-1. Claims procedure

(a) *Scope and purpose.* In accordance with the authority of sections 503 and 505 of the Employee Retirement Income Security Act of 1974 (ERISA or the Act), 29 U.S.C. 1133, 1135, this section sets forth minimum requirements for employee benefit plan procedures pertaining to claims for benefits by participants and beneficiaries (hereinafter referred to as claimants). Except as otherwise specifically provided in this section, these requirements apply to every employee benefit plan described in section 4(a) and not exempted under section 4(b) of the Act.

(b) *Obligation to establish and maintain reasonable claims procedures.* Every employee benefit plan shall establish and maintain reasonable procedures governing the filing of benefit claims, notification of benefit determinations, and appeal of adverse benefit determinations (hereinafter collectively referred to as claims procedures). The claims procedures for a plan will be deemed to be reasonable only if—

(1) The claims procedures comply with the requirements of paragraphs (c), (d), (e), (f), (g), (h), (i), and (j) of this section, as appropriate, except to the extent that the claims procedures are deemed to comply with some or all of such provisions pursuant to paragraph (b)(6) of this section;

(2) A description of all claims procedures (including, in the case of a group health plan within the meaning of paragraph (m)(6) of this section, any procedures for obtaining prior approval as a prerequisite for obtaining a

benefit, such as preauthorization procedures or utilization review procedures) and the applicable time frames is included as part of a summary plan description meeting the requirements of 29 CFR 2520.102-3;

(3) The claims procedures do not contain any provision, and are not administered in a way, that unduly inhibits or hampers the initiation or processing of claims for benefits. For example, a provision or practice that requires payment of a fee or costs as a condition to making a claim or to appealing an adverse benefit determination would be considered to unduly inhibit the initiation and processing of claims for benefits. Also, the denial of a claim for failure to obtain a prior approval under circumstances that would make obtaining such prior approval impossible or where application of the prior approval process could seriously jeopardize the life or health of the claimant (e.g., in the case of a group health plan, the claimant is unconscious and in need of immediate care at the time medical treatment is required) would constitute a practice that unduly inhibits the initiation and processing of a claim;

(4) The claims procedures do not preclude an authorized representative of a claimant from acting on behalf of such claimant in pursuing a benefit claim or appeal of an adverse benefit determination. Nevertheless, a plan may establish reasonable procedures for determining whether an individual has been authorized to act on behalf of a claimant, provided that, in the case of a claim involving urgent care, within the meaning of paragraph (m)(1) of this section, a health care professional, within the meaning of paragraph (m)(7) of this section, with knowledge of a claimant's medical condition shall be permitted to act as the authorized representative of the claimant; and

(5) The claims procedures contain administrative processes and safeguards designed to ensure and to verify that benefit claim determinations are made in accordance with governing plan documents and that, where appropriate,

the plan provisions have been applied consistently with respect to similarly situated claimants.

(6) In the case of a plan established and maintained pursuant to a collective bargaining agreement (other than a plan subject to the provisions of section 302(c)(5) of the Labor Management Relations Act, 1947 concerning joint representation on the board of trustees)—

(i) Such plan will be deemed to comply with the provisions of paragraphs (c) through (j) of this section if the collective bargaining agreement pursuant to which the plan is established or maintained sets forth or incorporates by specific reference—

(A) Provisions concerning the filing of benefit claims and the initial disposition of benefit claims, and

(B) A grievance and arbitration procedure to which adverse benefit determinations are subject.

(ii) Such plan will be deemed to comply with the provisions of paragraphs (h), (i), and (j) of this section (but will not be deemed to comply with paragraphs (c) through (g) of this section) if the collective bargaining agreement pursuant to which the plan is established or maintained sets forth or incorporates by specific reference a grievance and arbitration procedure to which adverse benefit determinations are subject (but not provisions concerning the filing and initial disposition of benefit claims).

(c) *Group health plans.* The claims procedures of a group health plan will be deemed to be reasonable only if, in addition to complying with the requirements of paragraph (b) of this section—

(1)(i) The claims procedures provide that, in the case of a failure by a claimant or an authorized representative of a claimant to follow the plan's procedures for filing a pre-service claim, within the meaning of paragraph (m)(2) of this section, the claimant or representative shall be notified of the failure and the proper procedures to be followed in filing a claim for benefits. This notification shall be provided to the claimant or authorized representative, as appropriate, as soon as possible, but not later than 5 days (24 hours in the case of a failure to file a claim involving urgent care) following the failure. Notification may be oral, unless written notification is requested by the claimant or authorized representative.

(ii) Paragraph (c)(1)(i) of this section shall apply only in the case of a failure that—

(A) Is a communication by a claimant or an authorized representative of a claimant that is received by a person or organizational unit customarily responsible for handling benefit matters; and

(B) Is a communication that names a specific claimant; a specific medical condition or symptom; and a specific treatment, service, or product for which approval is requested.

(2) The claims procedures do not contain any provision, and are not administered in a way, that requires a claimant to file more than two appeals of an adverse benefit determination prior to bringing a civil action under section 502(a) of the Act;

(3) To the extent that a plan offers voluntary levels of appeal (except to the extent that the plan is required to do so by State law), including voluntary arbitration or any other form of dispute resolution, in addition to those permitted by paragraph (c)(2) of this section, the claims procedures provide that:

(i) The plan waives any right to assert that a claimant has failed to exhaust administrative remedies because the claimant did not elect to submit a benefit dispute to any such voluntary level of appeal provided by the plan;

(ii) The plan agrees that any statute of limitations or other defense based on timeliness is tolled during the time that any such voluntary appeal is pending;

(iii) The claims procedures provide that a claimant may elect to submit a benefit dispute to such voluntary level of appeal only after exhaustion of the appeals permitted by paragraph (c)(2) of this section;

(iv) The plan provides to any claimant, upon request, sufficient information relating to the voluntary level of appeal to enable the claimant to make an informed judgment about whether to submit a benefit dispute to the voluntary level of appeal, including a statement that the decision of a claimant as to whether or not to submit a benefit dispute to the voluntary level of appeal will have no effect on the claimant's rights to any other benefits under the plan and information about the applicable rules, the claimant's right to representation, the process for selecting the decisionmaker, and the circumstances, if any, that may affect the impartiality of the decisionmaker, such as any financial or personal interests in the result or any past or present relationship with any party to the review process; and

(v) No fees or costs are imposed on the claimant as part of the voluntary level of appeal.

(4) The claims procedures do not contain any provision for the mandatory arbitration of adverse benefit determinations, except to the extent that the plan or procedures provide that:

(i) The arbitration is conducted as one of the two appeals described in paragraph (c)(2) of this section and in accordance with the requirements applicable to such appeals; and

(ii) The claimant is not precluded from challenging the decision under section 502(a) of the Act or other applicable law.

(d) *Plans providing disability benefits.* The claims procedures of a plan that provides disability benefits will be deemed to be reasonable only if the claims procedures comply, with respect to claims for disability benefits, with the requirements of paragraphs (b), (c)(2), (c)(3), and (c)(4) of this section.

(e) *Claim for benefits.* For purposes of this section, a claim for benefits is a request for a plan benefit or benefits made by a claimant in accordance with a plan's reasonable procedure for filing benefit claims. In the case of a group health plan, a claim for benefits includes any pre-service claims within the meaning of paragraph (m)(2) of this section and any post-service claims within the meaning of paragraph (m)(3) of this section.

(f) *Timing of notification of benefit determination.* (1) *In general.* Except as provided in paragraphs (f)(2) and (f)(3) of this section, if a claim is wholly or partially denied, the plan administrator shall notify the claimant, in accordance with paragraph (g) of this section, of the plan's adverse benefit determination within a reasonable period of time, but not later than 90 days after receipt of the claim by the plan, unless the plan administrator determines that special circumstances require an extension of time for processing the claim. If the plan administrator determines that an extension of time for processing is required, written notice of the extension shall be furnished to the claimant prior to the termination of the initial 90-day period. In no event shall such extension exceed a period of 90 days from the end of such initial period. The extension notice shall indicate the special circumstances requiring an extension of time and the date by which the plan expects to render the benefit determination.

(2) *Group health plans.* In the case of a group health plan, the plan administrator shall notify a claimant of the plan's benefit determination in accordance with paragraph (f)(2)(i), (f)(2)(ii), or (f)(2)(iii) of this section, as appropriate.

(i) *Urgent care claims*. In the case of a claim involving urgent care, the plan administrator shall notify the claimant of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim by the plan, unless the claimant fails to provide sufficient information to determine whether, or to what extent, benefits are covered or payable under the plan. In the case of such a failure, the plan administrator shall notify the claimant as soon as possible, but not later than 24 hours after receipt of the claim by the plan, of the specific information necessary to complete the claim. The claimant shall be afforded a reasonable amount of time, taking into account the circumstances, but not less than 48 hours, to provide the specified information. Notification of any adverse benefit determination pursuant to this paragraph (f)(2)(i) shall be made in accordance with paragraph (g) of this section. The plan administrator shall notify the claimant of the plan's benefit determination as soon as possible, but in no case later than 48 hours after the earlier of—

(A) The plan's receipt of the specified information, or

(B) The end of the period afforded the claimant to provide the specified additional information.

(ii) *Concurrent care decisions*. If a group health plan has approved an ongoing course of treatment to be provided over a period of time or number of treatments—

(A) Any reduction or termination by the plan of such course of treatment (other than by plan amendment or termination) before the end of such period of time or number of treatments shall constitute an adverse benefit determination. The plan administrator shall notify the claimant, in accordance with paragraph (g) of this section, of the

adverse benefit determination at a time sufficiently in advance of the reduction or termination to allow the claimant to appeal and obtain a determination on review of that adverse benefit determination before the benefit is reduced or terminated.

(B) Any request by a claimant to extend the course of treatment beyond the period of time or number of treatments that is a claim involving urgent care shall be decided as soon as possible, taking into account the medical exigencies, and the plan administrator shall notify the claimant of the benefit determination, whether adverse or not, within 24 hours after receipt of the claim by the plan, provided that any such claim is made to the plan at least 24 hours prior to the expiration of the prescribed period of time or number of treatments. Notification of any adverse benefit determination concerning a request to extend the course of treatment, whether involving urgent care or not, shall be made in accordance with paragraph (g) of this section, and appeal shall be governed by paragraph (i)(2)(i), (i)(2)(ii), or (i)(2)(iii), as appropriate.

(iii) *Other claims*. In the case of a claim not described in paragraphs (f)(2)(i) or (f)(2)(ii) of this section, the plan administrator shall notify the claimant of the plan's benefit determination in accordance with either paragraph (f)(2)(iii)(A) or (f)(2)(iii)(B) of this section, as appropriate.

(A) *Pre-service claims*. In the case of a pre-service claim, the plan administrator shall notify the claimant of the plan's benefit determination (whether adverse or not) within a reasonable period of time appropriate to the medical circumstances, but not later than 15 days after receipt of the claim by the plan. This period may be extended one time by the plan for up to 15 days,

provided that the plan administrator both determines that such an extension is necessary due to matters beyond the control of the plan and notifies the claimant, prior to the expiration of the initial 15-day period, of the circumstances requiring the extension f time and the date by which the plan expects to render a decision. If such an extension is necessary due to a failure of the claimant to submit the information necessary to decide the claim, the notice of extension shall specifically describe the required information, and the claimant shall be afforded at least 45 days from receipt of the notice within which to provide the specified information. Notification of any adverse benefit determination pursuant to this paragraph (f)(2)(iii)(A) shall be made in accordance with paragraph (g) of this section.

(B) *Post-service claims*. In the case of a post-service claim, the plan administrator shall notify the claimant, in accordance with paragraph (g) of this section, of the plan's adverse benefit determination within a reasonable period of time, but not later than 30 days after receipt of the claim. This period may be extended one time by the plan for up to 15 days, provided that the plan administrator both determines that such an extension is necessary due to matters beyond the control of the plan and notifies the claimant, prior to the expiration of the initial 30-day period, of the circumstances requiring the extension of time and the date by which the plan expects to render a decision. If such an extension is necessary due to a failure of the claimant to submit the information necessary to decide the claim, the notice of extension shall specifically describe the required information, and the claimant shall be afforded at least 45 days from receipt of the notice within which to provide the specified information.

(3) *Disability claims*. In the case of a claim for disability benefits, the plan administrator shall notify the claimant, in accordance with paragraph (g) of this section, of the plan's adverse benefit determination within a reasonable period of time, but not later than 45 days after receipt of the claim by the plan. This period may be extended by the plan for up to 30 days, provided that the plan administrator both determines that such an extension is necessary due to matters beyond the control of the plan and notifies the claimant, prior to the expiration of the initial 45-day period, of the circumstances requiring the extension of time and the date by which the plan expects to render a decision. If, prior to the end of the first 30-day extension period, the administrator determines that, due to matters beyond the control of the plan, a decision cannot be rendered within that extension period, the period for making the determination may be extended for up to an additional 30 days, provided that the plan administrator notifies the claimant, prior to the expiration of the first 30-day extension period, of the circumstances requiring the extension and the date as of which the plan expects to render a decision. In the case of any extension under this paragraph (f)(3), the notice of extension shall specifically explain the standards on which entitlement to a benefit is based, the unresolved issues that prevent a decision on the claim, and the additional information needed to resolve those issues, and the claimant shall be afforded at least 45 days within which to provide the specified information.

(4) *Calculating time periods*. For purposes of paragraph (f) of this section, the period of time within which a benefit determination is required to be made shall begin at the time a claim is filed in accordance with the reasonable procedures of a plan, without regard to whether all the information necessary to make a benefit determination accompanies the filing. In the event that a period of time is extended as permitted pursuant to paragraph (f)(2)(iii) or (f)(3) of this section due to a claimant's failure to submit information necessary to decide a claim, the period for making the benefit determination shall be tolled from the

date on which the notification of the extension is sent to the claimant until the date on which the claimant responds to the request for additional information.

(g) *Manner and content of notification of benefit determination.* (1) Except as provided in paragraph (g)(2) of this section, the plan administrator shall provide a claimant with written or electronic notification of any adverse benefit determination. Any electronic notification shall comply with the standards imposed by 29 CFR 2520.104b-1(c)(1)(i), (iii), and (iv). The notification shall set forth, in a manner calculated to be understood by the claimant—

(i) The specific reason or reasons for the adverse determination;

(ii) Reference to the specific plan provisions on which the determination is based;

(iii) A description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary;

(iv) A description of the plan's review procedures and the time limits applicable to such procedures, including a statement of the claimant's right to bring a civil action under section 502(a) of the Act following an adverse benefit determination on review;

(v) In the case of an adverse benefit determination by a group health plan or a plan providing disability benefits,

(A) If an internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination, either the specific rule, guideline, protocol, or other similar criterion; or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be

provided free of charge to the claimant upon request; or

(B) If the adverse benefit determination is based on a medical necessity or experimental treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request.

(vi) In the case of an adverse benefit determination by a group health plan concerning a claim involving urgent care, a description of the expedited review process applicable to such claims.

(2) In the case of an adverse benefit determination by a group health plan concerning a claim involving urgent care, the information described in paragraph (g)(1) of this section may be provided to the claimant orally within the time frame prescribed in paragraph (f)(2)(i) of this section, provided that a written or electronic notification in accordance with paragraph (g)(1) of this section is furnished to the claimant not later than 3 days after the oral notification.

(h) *Appeal of adverse benefit determinations.* (1) *In general.* Every employee benefit plan shall establish and maintain a procedure by which a claimant shall have a reasonable opportunity to appeal an adverse benefit determination to an appropriate named fiduciary of the plan, and under which there will be a full and fair review of the claim and the adverse benefit determination.

(2) *Full and fair review.* Except as provided in paragraphs (h)(3) and (h)(4) of this section, the claims procedures of a plan will not be deemed to provide a claimant with a reasonable opportunity for a full and fair review of a claim and adverse benefit determination unless the claims procedures—

(i) Provide claimants at least 60 days following receipt of a notification of an adverse benefit determination within which to appeal the determination;

(ii) Provide claimants the opportunity to submit written comments, documents, records, and other information relating to the claim for benefits;

(iii) Provide that a claimant shall be provided, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the claimant's claim for benefits. Whether a document, record, or other information is relevant to a claim for benefits shall be determined by reference to paragraph (m)(8) of this section;

(iv) Provide for a review that takes into account all comments, documents, records, and other information submitted by the claimant relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination.

(3) *Group health plans.* The claims procedures of a group health plan will not be deemed to provide a claimant with a reasonable opportunity for a full and fair review of a claim and adverse benefit determination unless, in addition to complying with the requirements of paragraphs (h)(2)(ii) through (iv) of this section, the claims procedures—

(i) Provide claimants at least 180 days following receipt of a notification of an adverse benefit determination within which to appeal the determination;

(ii) Provide for a review that does not afford deference to the initial adverse benefit determination and that is conducted by an appropriate named fiduciary of the plan who is neither the individual who made

the adverse benefit determination that is the subject of the appeal, nor the subordinate of such individual;

(iii) Provide that, in deciding an appeal of any adverse benefit determination that is based in whole or in part on a medical judgment, including determinations with regard to whether a particular treatment, drug, or other item is experimental, investigational, or not medically necessary or appropriate, the appropriate named fiduciary shall consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment;

(iv) Provide for the identification of medical or vocational experts whose advice was obtained on behalf of the plan in connection with a claimant's adverse benefit determination, without regard to whether the advice was relied upon in making the benefit determination;

(v) Provide that the health care professional engaged for purposes of a consultation under paragraph (h)(3)(iii) of this section shall be an individual who is neither an individual who was consulted in connection with the adverse benefit determination that is the subject of the appeal, nor the subordinate of any such individual; and

(vi) Provide, in the case of a claim involving urgent care, for an expedited review process pursuant to which—

(A) A request for an expedited appeal of an adverse benefit determination may be submitted orally or in writing by the claimant; and

(B) All necessary information, including the plan's benefit determination on review, shall be transmitted between the plan and the claimant by telephone, facsimile, or other available similarly expeditious method.

(4) *Plans providing disability benefits*. The claims procedures of a plan providing disability benefits will not, with respect to claims for such benefits, be deemed to provide a claimant with a reasonable opportunity for a full and fair review of a claim and adverse benefit determination unless the claims procedures comply with the requirements of paragraphs (h)(2)(ii) through (iv) and (h)(3)(i) through (v) of this section.

(i) *Timing of notification of benefit determination on review*. (1) *In general*. (i) Except as provided in paragraphs (i)(1)(ii), (i)(2), and (i)(3) of this section, the plan administrator shall notify a claimant in accordance with paragraph (j) of this section of the plan's benefit determination on review within a reasonable period of time, but not later than 60 days after receipt of the claimant's request for review by the plan, unless the plan administrator determines that special circumstances (such as the need to hold a hearing, if the plan's procedures provide for a hearing) require an extension of time for processing the claim. If the plan administrator determines that an extension of time for processing is required, written notice of the extension shall be furnished to the claimant prior to the termination of the initial 60-day period. In no event shall such extension exceed a period of 60 days from the end of the initial period. The extension notice shall indicate the special circumstances requiring an extension of time and the date by which the plan expects to render the determination on review.

(ii) In the case of a plan with a committee or board of trustees designated as the appropriate named fiduciary that holds regularly scheduled meetings at least quarterly, paragraph (i)(1)(i) of this section shall not apply, and, except as provided in paragraphs (i)(2) and (i)(3) of this section, the appropriate named fiduciary shall instead make a benefit determination no later than the date of the meeting of the committee or board that immediately follows the plan's receipt of a request for review, unless the request for review is filed within 30 days preceding the date of such meeting. In such case, a benefit determination may be made by no later than the date of the second meeting following the plan's receipt of the request for review. If special circumstances (such as the need to hold a hearing, if the plan's procedures provide for a hearing) require a further extension of time for processing, a benefit determination shall be rendered not later than the third meeting of the committee or board following the plan's receipt of the request for review. If such an extension of time for review is required because of special circumstances, the plan administrator shall provide the claimant with written notice of the extension, describing the special circumstances and the date as of which the benefit determination will be made, prior to the commencement of the extension. The plan administrator shall notify the claimant, in accordance with paragraph (j) of this section, of the benefit determination as soon as possible, but not later than 5 days after the benefit determination is made.

(2) *Group health plans*. In the case of a group health plan, the plan administrator shall notify a claimant of the plan's benefit determination on review in accordance with paragraphs (i)(2)(i) through (iii), as appropriate.

(i) *Urgent care claims*. In the case of a claim involving urgent care, the plan administrator shall notify the claimant, in accordance with paragraph (j) of this section, of the plan's benefit determination on review as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claimant's request for review of an adverse benefit determination by the plan.

(ii) *Pre-service claims*. In the case of a pre-service claim, the plan administrator shall notify the claimant, in accordance with paragraph (j) of this section, of the plan's benefit determination on review within a reasonable period of time appropriate to the medical circumstances. In the case of a group health plan that

provides for one appeal of an adverse benefit determination, such notification shall be provided not later than 30 days after receipt by the plan of the claimant's request for review of an adverse benefit determination. In the case of a group health plan that provides for two appeals of an adverse determination, such notification shall be provided, with respect to any one of such two appeals, not later than 15 days after receipt by the plan of the claimant's request for review of the adverse determination.

(iii) *Post-service claims.* (A) In the case of a post-service claim, except as provided in paragraph (i)(2)(iii)(B) of this section, the plan administrator shall notify the claimant, in accordance with paragraph (j) of this section, of the plan's benefit determination on review within a reasonable period of time. In the case of a group health plan that provides for one appeal of an adverse benefit determination, such notification shall be provided not later than 60 days after receipt by the plan of the claimant's request for review of an adverse benefit determination. In the case of a group health plan that provides for two appeals of an adverse determination, such notification shall be provided, with respect to any one of such two appeals, not later than 30 days after receipt by the plan of the claimant's request for review of the adverse determination.

(B) In the case of a multiemployer plan with a committee or board of trustees designated as the appropriate named fiduciary that holds regularly scheduled meetings at least quarterly, paragraph (i)(2)(iii)(A) of this section shall not apply, and the appropriate named fiduciary shall instead make a benefit determination no later than the date of the meeting of the committee or board that immediately follows the plan's receipt of a request for review, unless the request for review is filed within 30 days preceding the date of such meeting. In

such case, a benefit determination may be made by no later than the date of the second meeting following the plan's receipt of the request for review. If special circumstances (such as the need to hold a hearing, if the plan's procedures provide for a hearing) require a further extension of time for processing, a benefit determination shall be rendered not later than the third meeting of the committee or board following the plan's receipt of the request for review. If such an extension of time for review is required because of special circumstances, the plan administrator shall notify the claimant in writing of the extension, describing the special circumstances and the date as of which the benefit determination will be made, prior to the commencement of the extension. The plan administrator shall notify the claimant, in accordance with paragraph (j) of this section, of the benefit determination as soon as possible, but not later than 5 days after the benefit determination is made.

(3) *Disability claims.* (i) Except as provided in paragraph (i)(3)(ii) of this section, claims involving disability benefits (whether the plan provides for one or two appeals) shall be governed by paragraph (i)(1) of this section, except that a period of 45 days shall apply instead of 60 days for purposes of that paragraph.

(ii) In the case of a multiemployer plan with a committee or board of trustees designated as the appropriate named fiduciary that holds regularly scheduled meetings at least quarterly, paragraph (i)(3)(i) of this section shall not apply, and the appropriate named fiduciary shall instead make a benefit determination no later than the date of the meeting of the committee or board that immediately follows the plan's receipt of a request for review, unless the request for review is filed within 30 days preceding the date of such meeting. In such case, a benefit determination may be made by no later than the date of the second meeting

following the plan's receipt of the request for review. If special circumstances (such as the need to hold a hearing, if the plan's procedures provide for a hearing) require a further extension of time for processing, a benefit determination shall be rendered not later than the third meeting of the committee or board following the plan's receipt of the request for review. If such an extension of time for review is required because of special circumstances, the plan administrator shall notify the claimant in writing of the extension, describing the special circumstances and the date as of which the benefit determination will be made, prior to the commencement of the extension. The plan administrator shall notify the claimant, in accordance with paragraph (j) of this section, of the benefit determination as soon as possible, but not later than 5 days after the benefit determination is made.

(4) *Calculating time periods*. For purposes of paragraph (i) of this section, the period of time within which a benefit determination on review is required to be made shall begin at the time an appeal is filed in accordance with the reasonable procedures of a plan, without regard to whether all the information necessary to make a benefit determination on review accompanies the filing. In the event that a period of time is extended as permitted pursuant to paragraph (i)(1), (i)(2)(iii)(B), or (i)(3) of this section due to a claimant's failure to submit information necessary to decide a claim, the period for making the benefit determination on review shall be tolled from the date on which the notification of the extension is sent to the claimant until the date on which the claimant responds to the request for additional information.

(5) *Furnishing documents*. In the case of an adverse benefit determination on review, the plan administrator shall provide such access to and copies of, documents, records, and other information described in paragraphs (j)(3), (j)(4), and (j)(5) of this section as is appropriate.

(j) *Manner and content of notification of benefit determination on review*. The plan administrator shall provide a claimant with written or electronic notification of a plan's benefit determination on review. Any electronic notification shall comply with the standards imposed by 29 CFR 2520.104b-1(c)(1)(i), (iii), and (iv). In the case of an adverse benefit determination, the notification shall set forth, in a manner calculated to be understood by the claimant—

(1) The specific reason or reasons for the adverse determination;

(2) Reference to the specific plan provisions on which the benefit determination is based;

(3) A statement that the claimant is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the claimant's claim for benefits. Whether a document, record, or other information is relevant to a claim for benefits shall be determined by reference to paragraph (m)(8) of this section;

(4) A statement describing any voluntary appeal procedures offered by the plan and the claimant's right to obtain the information about such procedures described in paragraph (c)(3)(iv) of this section, and a statement of the claimant's right to bring an action under section 502(a) of the Act; and

(5) In the case of a group health plan or a plan providing disability benefits—

(i) If an internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination, either the specific rule, guideline, protocol, or other similar criterion; or a statement that such rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of the rule, guideline, protocol, or other similar criterion will be provided free of charge to the claimant upon request;

(ii) If the adverse benefit determination is based on a medical necessity or experimental treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request; and

(iii) The following statement: "You and your plan may have other voluntary alternative dispute resolution options, such as mediation. One way to find out what may be available is to contact your local U.S. Department of Labor Office and your State insurance regulatory agency."

(k) *Preemption of State law.* (1) Nothing in this section shall be construed to supersede any provision of State law that regulates insurance, except to the extent that such law prevents the application of a requirement of this section.

(2)(i) For purposes of paragraph (k)(1) of this section, a State law regulating insurance shall not be considered to prevent the application of a requirement of this section merely because such State law establishes a review procedure to evaluate and resolve disputes involving adverse benefit determinations under group health plans so long as the review procedure is conducted by a person or entity other than the insurer, the plan, plan fiduciaries, the employer, or any employee or agent of any of the foregoing.

(ii) The State law procedures described in paragraph (k)(2)(i) of this section are not part of the full and fair review required by section 503 of the Act. Claimants therefore need not exhaust such State law procedures prior to bringing suit under section 502(a) of the Act.

(*l*) *Failure to establish and follow reasonable claims procedures.* In the case of the failure of a plan to establish or follow claims procedures consistent with the requirements of this section, a claimant shall be deemed to have exhausted the administrative remedies available under the plan and shall

be entitled to pursue any available remedies under section 502(a) of the Act on the basis that the plan has failed to provide a reasonable claims procedure that would yield a decision on the merits of the claim.

(m) *Definitions.* The following terms shall have the meaning ascribed to such terms in this paragraph (m) whenever such term is used in this section:

(1) (i) A "claim involving urgent care" is any claim for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations—

(A) Could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function, or,

(B) In the opinion of a physician with knowledge of the claimant's medical condition, would subject the claimant to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim.

(ii) Except as provided in paragraph (m)(1)(iii) of this section, whether a claim is a "claim involving urgent care" within the meaning of paragraph (m)(1)(i)(A) of this section is to be determined by an individual acting on behalf of the plan applying the judgment of a prudent layperson who possesses an average knowledge of health and medicine.

(iii) Any claim that a physician with knowledge of the claimant's medical condition determines is a "claim involving urgent care" within the meaning of paragraph (m)(1)(i) of this section shall be treated as a "claim involving urgent care" for purposes of this section.

(2) The term "pre-service claim" means any claim for a benefit under a group health plan with respect to which the terms of the plan condition receipt of the benefit, in

whole or in part, on approval of the benefit in advance of obtaining medical care.

(3) The term "post-service claim" means any claim for a benefit under a group health plan that is not a pre-service claim within the meaning of paragraph (m)(2) of this section.

(4) The term "adverse benefit determination" means any of the following: a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit, including any such denial, reduction, termination, or failure to provide or make payment that is based on a determination of a participant's or beneficiary's eligibility to participate in a plan, and including, with respect to group health plans, a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit resulting from the application of any utilization review, as well as a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.

(5) The term "notice" or "notification" means the delivery or furnishing of information to an individual in a manner that satisfies the standards of 29 CFR 2520.104b-1(b) as appropriate with respect to material required to be furnished or made available to an individual.

(6) The term "group health plan" means an employee welfare benefit plan within the meaning of section 3(1) of the Act to the extent that such plan provides "medical care" within the meaning of section 733(a) of the Act.

(7) The term "health care professional" means a physician or other health care professional licensed, accredited, or certified to perform specified health services consistent with State law.

(8) A document, record, or other information shall be considered "relevant" to a claimant's claim if such document, record, or other information

(i) Was relied upon in making the benefit determination;

(ii) Was submitted, considered, or generated in the course of making the benefit determination, without regard to whether such document, record, or other information was relied upon in making the benefit determination;

(iii) Demonstrates compliance with the administrative processes and safeguards required pursuant to paragraph (b)(5) of this section in making the benefit determination; or

(iv) In the case of a group health plan or a plan providing disability benefits, constitutes a statement of policy or guidance with respect to the plan concerning the denied treatment option or benefit for the claimant's diagnosis, without regard to whether such advice or statement was relied upon in making the benefit determination.

(n) *Apprenticeship plans.* This section does not apply to employee benefit plans that solely provide apprenticeship training benefits.

(o) *Applicability dates.* (1) Except as provided in paragraph (o)(2) of this section, this section shall apply to claims filed under a plan on or after January 1, 2002.

(2) This section shall apply to claims filed under a group health plan on or after the first day of the first plan year beginning on or after July 1, 2002, but in no event later than January 1, 2003.

MEMBER MEDICATION FORMULARY GUIDE

January 2000

Aetna US Healthcare

INTRODUCTION

Aetna U.S. Healthcare's *Medication Formulary Guide* lists the "preferred" generic and brand-name medications available through your prescription drug benefit plan.* These medications are referred to as "formulary" medications.

It's important to note that other nonpreferred (nonformulary) medications not listed may also be covered under your prescription drug benefits. Please refer to your plan documents for details.

The Formulary Exclusions, Precertification and Step-Therapy lists apply to some benefit plans. Please refer to these sections of the *Formulary Guide* and to your plan documents for further information.

How are drugs selected for the Aetna U.S. Healthcare formulary (preferred drug list)?

Our goal is to provide a formulary that gives members access to quality medications. The FDA-approved brand-name and generic drugs chosen for our formulary are selected based on their safety, effectiveness and overall value.

When choosing drugs for our formulary, Aetna U.S. Healthcare's Pharmacy Quality Advisory Committee (PQAC) and Pharmacy and Therapeutics (P&T) Committee each meet regularly to review drugs that have been approved by the FDA. The PQAC reviews available literature and other clinical information, and provides qualitative comments re-

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* Some medications, such as oral contraceptives and infertiliy medications, may not be covered for all members. Please check your plan document for details.

garding the drugs being reviewed to the P&T Committee. The PQAC is comprised of participating providers in active clinical practice from a variety of specialties and from different locations in the United States.

After evaluating information from different sources, the P&T Committee places medications in one of three categories:

Category I—The drug represents an important therapeutic advance. These drugs are always included on the formulary.

Category II—The drug is clinically and therapeutically similar to other available products. These drugs are further reviewed by Aetna U.S. Healthcare for overall value.

Category III—The drug has significant disadvantages in safety or efficacy when compared to other similar products. These drugs are always excluded from the formulary.

Generic drugs are therapeutically equivalent to their brand-name counterparts. They contain the same active ingredients in the same amounts as the brand-name drug. Also, generic drugs undergo the same rigorous FDA quality and safety reviews as brand-name medications. As such, generics are effective, safe alternatives to brand-name medications.

In addition, using generic drugs may help lower your health care expenses. Under some Aetna U.S. Healthcare prescription drug benefit plans, members pay a lower-copayment if they choose generic drugs over brand-name medications, which means lower out-of-pocket costs for them.

Should I share this *Formulary Guide* with my physician?

Yes. We encourage you to share the *Formulary Guide* with your physicians and take it with you each time you visit them. The *Formulary Guide* helps you talk with your physician about medication alternatives, such as less expensive brand-name and generic drugs. Please ask your doctors to

consider the medications in your *Formulary Guide* when they prescribe medications for you.

What if I have questions?

If you have any further questions about the *Formulary Guide* or your prescription drug benefits, please call the Member Services number on your ID card. (TDD 800-501-9863 for hearing impaired members.) If you have questions about specific medications, please consult with your physician.

We wish you good health.

The medications listed in the Aetna U.S. Healthcare *Medication Formulary Guide* are subject to change without prior notification. If you have access to the Internet, you can obtain the most current version of the *Formulary Guide* through Aetna U.S. Healthcare's website: www.aetnaushc.com/products/rx/index.html.

THE AETNA U.S. HEALTHCARE FORMULARY

The following is a list of "preferred" medications that are covered under your pharmacy benefit plan.* Medications not listed may also be covered, depending on your plan design.

Please note that the dollar signs ($) listed next to the drugs provide comparative cost information to educate members who may not be familiar with the relative costs of sinilar medications.

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* Some medications, for example oral contraceptives, may only be covered if additional, optional coverage has been added to your standard prescription drug benefit plan. Please refer to your plan documents for further information.

Key

Bold = Brand name of drug
italics = Generic name of drug
* = Recommended generic substitution for brand-name drug
QL = Quantity limit for some benefit plans
PR = Precertification may apply
ST = Step-therapy may apply

* * * *

Muscle and Skeleton

OSTEOPOROSIS

$$$	**Didronel** *(etidronate)*
$$$	**Fosamax** *(alendronate sodium)*
$$$$$	**Skelid** *(tiludronate)* **PR**
$$$$$	**Acotonel** *(risedronate)* **PR**

PAIN AND INFLAMMATION

$	*ibuprofen* (strengths > 200 mg)*
$	*indeomethacin**
$	*piroxicam**
$	*naproxen**
$$	*salsalate**
$$	*sulindac**
$$	*fenoprofen**
$$	*meclofenamate**
$$$	*indomethacin SR**
$$$	*tolmetin**
$$$	*choline Mg trisalicylate**
$$$	*ketoprofen**
$$$$	*etodolac**
$$$$	*flurbiprofen**
$$$$$	*diclofenac**

$$$$$	**Celebrex** *(celecoxib)* **PR, ST**
$$$$$	**Vioxx** *(rofecoxib)* **PR, ST**

PAIN AND INFLAMMATION COMBINATION____

$$$$	**Arthrotec** *(diclofenac/misoprostol)*

ARTHRITIS _____

$	*sulfasalazine**
$$$	*hydroxychloroquine**
$$$$	**Cuprimine** *(penicillamine)*
$$$$	**Ridaura** *(auranofin)*
$$$$$$$	**Arava** *(leflunomide)*

* * * *

PRECERTIFICATION LIST

The following medications require precertification under most pharmacy benefit plans. Precertification helps encourage appropriate use of certain drugs in accordance with current medical literature, manufacturer recommendations and Food and Drug Administration (FDA) guidelines. The precertification requirement applies to medications that people are more likely to take inappropriately or use in amounts that exceed dosage or length of treatment recommendations. If precertification applies to your benefit plan, your doctor must contact the Pharmacy Management Precertification Unit to request prior authorization for the medication. If the request is approved, the drug will be covered.

The drugs requiring precertification are subject to change.

If you have questions about which pharmacy benefit plan you have or whether this list applies to you, please call the Member Services number on your ID card. (TDD 800-501-9863 for hearing impaired members.)

Note: Some HMO plans may cover injectable medications through the medical benefit.

Noninjectable Medications

Accolate *(zafirlukast)*

Accutane *(isotretinoin)*

Actonel *(risedronate)*

Adderall *(amphetamine-dextroamphetamine)* for members > 18 years old

Amerge *(naratriptan)* 1mg tabs > 27 per month, 2.5 mg tabs > 9 per month

Atacand *(candesartan)*

Avalide *(irbesartanlhctz)*

Avapro *(irbesartan)*

Avita *(tretionoin topical)* for members > 36 years old

Azopt *(brinzolamide)*

Caverject *(alprostadil)* > 6 per month

Celebrex *(celecoxib)*

Coreg *(carvedilol)*

Cosopt *(dorzolamide/timolol)*

Cozaar *(losartan)*

Cylert *(pemoline)* for members > 18 years old

DDAVP *(desmopressin) tabs, nasal* > 8 weeks of therapy

Desoxyn *(methamphetarnine)* for members > 18 years old

Dexedrine *(dextroamphetamine)* for members > 18 years old

Dextrostat *(dextroamphetamine)* for members > 18 years old)

Diflucan *(fluconazole)* single dose of 150 mg covered without precertification

Diovan *(valsartan)*

Diovan HCT *(valsartan/hctz)*

Estring *(estradiol)* > 1 per 90 days

Helidac *(bismuth subsalicylate, metronidazole, tetracycline)* > 14 per year

Hyzaar *(losartan/hctz)*

Imitrex *(sumatriptan)* nasal > 1 pkg of 6 bottles per month, 50 mg tabs > 27 per month, 25 mg tabs > 45 per month

Infertility Medications (if a covered benefit for the group)

Lamisil *(terbinafine tab)*

Maxalt *(rizatriptan)* 5 mg tabs > 24 per month, 10 mg tabs > 12 per month

Micardis *(telmisartan)*

Muse *(alprostadil)* > 6 per month

Prevpac *(amoxicillin, clarithromycin, lansoprazole)* > 14 per year

Retin-A/micro *(tretinoin topical)* for members > 36 years old

Rezulin *(troglitazone)*

Ritalin *(methylphenidate)* for members > 18 years old

Singulair *(montelukast)*

Skelid *(tiludronate)*

Sporanox *(itraconazole)*

Stadol NS *(butorphanol)* > 2 per month

Tritec *(ranitidine/bismuth citrate)* > 28 per year

Trusopt *(dorzolamide)*

Ultram *(tramadol)*

Vesanoid *(tretinoin)*

Vioxx *(rofecoxib)*

Wellbutrin SR *(bupropion)* 150 mg only

Zagam *(sparfloxacin)*

Zomig *(zolmitriptan)* 2.5 mg tabs > 18 per month, 5 mg tabs > 9 per month

Injectable Medications

Actimmune *(interferon gamma-1B)* for nonmalignancy

Alferon N *(interferon alfa-N3)* for nonmalignancy

Avonex *(interferon beta 1-A)*

Betaseron *(interferon beta 1-B)*

Ceredase *(alglucerase)*

Cerezyme *(imglucerase)*

Depo-Provera *(medroxyprogesterone)*

Epogen *(erythropoietin)*

Flolan *(epoprostenol)*

Growth Hormones (if a covered benefit for the group)

Humalog *(insulin lispro)*

Human Chorionic Gonadotropin

Hyalgan *(hyaluronate)*

Imitrex *(sumatriptan)* > 4 kits per month

Infergen *(interferon alfacon-1)* for nonmalignancy

Infertility Medications (if a covered benefit for the group)

Intravenous Immunoglobulin (IGIV, IGG)

Intron-A *(interferon alfa-2B)* for nonmalignancy

Lupron *(leuprolide)*

Procrit *(erythropoietin)*

Prolastin *(alpha-1-antitrypsin)*

Roferon-A *(interferon alfa-2A)* for nonmalignancy

Synvisc *(hyaluronate)*

Zoladex *(goserelin)*

FOR CALIFORNIA ONLY: all self-injectable drugs require precertification.

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STEP-THERAPY LIST

Drugs on the Step-Therapy List are subject to a different form of Precertification requirement under most pharmacy benefit plans. If step-therapy applies to your benefit plan, you must try one or more "prerequisite therapy" medications before a "step-therapy" medication will be covered. However, if it is medically necessary for you to be initially treated with a step-therapy medication, your doctor can contact the Pharmacy Management Precertification Unit to request coverage as a medical exception. If the request is approved, the drug will be covered.

For example, Zestril is a step-therapy medication that requires one prerequisite therapy medication. Zestril will not be covered under most benefit plans unless Prinivil has first been tried. However, if it is medically necessary for you to be treated with Zestril, your doctor can contact the Pharmacy Management Precertification Unit to request coverage.

Axid is a step-therapy medication that requires two prerequisite therapy medications. Axid will not be covered under most benefit plans unless cimetidine and ranitidine have each been tried. However, if it is medically necessary for you to be treated with Axid, your doctor can contact the Pharmacy Management Precertification Unit to request coverage.

The drugs on the Step-Therapy List are subject to change.

If you have questions about which pharmacy benefit plan you have or whether this list applies to you, please call the Member Services number on your ID card. (TDD 800-501-9863 for hearing impaired members.)

Step-Therapy Medications	Prerequisate Therapy
Accolate *(zafirlukast)*	any inhaled antiinflammatory agent (e.g. **Pulmicort, Flovent, Vanceril/DS, Azmacort**); and an inhaled bronchodilator (e.g. *albuterol,* **Tornalate, Alupent, Proventil HFA**, *ipratropium,* **Atrovent, Combivent, Maxair**)
Alora *(estradiol patch)*	any oral estrogen (e.g: *estradiol, estropipate,* **Estratab, Premphase, Prempro, Premarin**); and **Estraderm**; and **Vivelle/DOT**
Amaryl *(glimepiride)*	any generic oral hypoglycemic (e.g. *tolazamide, tolbutamide, glipizide, glyburide, chlorpropamide, acetohexamide)*
Atacand *(candesartan)*	any angiotensin converting enzyme inhibitor (e.g. *captopril,* **Prinivil, Accupril**); and **Cozaar**, and **Diovan**
Avalide *(irbesartan/hctz)*	any angiotensin converting enzyme inhibitor (e.g. *captopril,* **Prinivil, Accupril**); and **Hyzaar**, and **Diovan HCT**
Avapro *(irbesartan)*	any angiotensin converting enzyme inhibitor (e.g, *captopril,* **Prinivil, Accupril**); and **Cozaar**, and **Diovan**
Axid *(nizatidine)*	*cimetidine;* and *ranitidine*

Azopt *(brinzolamide)*	any ophthalmic beta blocker (e.g. *levobunolol, timolol,* **Ocupress, Betimol, Betoptic-S)**
Baycol *(cerivastatin)*	maximum doses of **Lescol** and/or **Zocor**
Celebrex *(celecoxib)*	any two generic NSAIDs (e.g. *ibuprofen, naproxen, salsalate, choline MG trisalicylate, piroxicam, sulindac, fenoprofen, meclofenamate, tolmetin, etodolac, diclofenac, ketoprofen, flurbiprofen)*
Climara *(estradiol patch)*	any oral estrogen (e.g., *estradiol, estropipate,* **Estratab**; **Premphase, Prempro, Premarin**); and **Estraderm**, and **Vivelle/DOT**
CombiPatch *(estradiol patch/norethindrone)*	any oral estrogen (e.g., *estradiol, estropipate,* **Estratab**; **Premphase, Prempro, Premarin**); and **Estraderm**, and **Vivelle/DOT**
Coreg *(carvedilol)*	**Lanoxin** and any angiotensin coverting enzyme inhibitor (e.g. *captopril,* **Prinivil, Accupril)**
Cosopt *(dorzolamide/ timolol)*	any ophthalmic beta blocker (e.g. *levobunolol, timolol,* **Ocupress, Betimol, Betoptic-S**); and **Azopt**
Cozaar *(losartan)*	any angiotensin converting enzyme inhibitor (e.g. *captopril,* **Prinivil, Accupril)**

Daypro *(oxaprozin)*	any two generic NSAIDs (e.g. *ibuprofen, naproxen, salsalate, choline MG trisalicylate, piroxicam, sulindac, fenoprofen, meclofenamate, tolmetin, etodolac, diclofenac, ketoprofen, flurbiprofen)*
Diovan *(valsartan)*	any angiotensin converting enzyme inhibitor (e.g. *captopril,* **Prinivil, Accupril)**
Diovan HCT *(valsartan/hctz)*	any angiotensin converting enzyme inhibitor (e.g. *captopril,* **Prinivil, Accupril)**
Estraderm *(estradiol patch)*	any oral estrogen (e.g. *estradiol, estropipate,* **Estratab, Premphase, Prempro, Premarin)**
FemPatch *(estradiol patch)*	any oral estrogen (e.g. *estradiol, estropipate,* **Estratab, Premphase, Prempro, Premarin**); and **Estraderm**; and **Vivelle/DOT**
Glucophage *(metformin)*	any generic oral hypoglycemic (e.g. *tolazamide, tolbutamide, glipizide, glyburide, chlorpropamide, acetohexamide)*
Hyzaar *(losartan/hctz)*	any angiotensin converting enzyme inhibitor (e.g. *captopril,* **Prinivil, Accupril)**
Lexxel *(enalapril/ felodipine)*	any single agent formulary ACE inhibitor or Calcium Channel Blocker; and **Lotrel**
Lipitor *(atorvastatin)*	maximum doses of **Lescol** and/or **Zocor**

Lodine XL *(etodolac)*	any two generic NSAIDS (e.g. *ibuprofen, naproxen, salsalate, choline Mg trisalicylate, piroxicam, sulindac, fenoprofen, meclofenamate, tolmetin, etodolac; diclofenac, ketoprofen, flurbiprofen)*
Lotrel *(amlodipine/ benazapril)*	any single agent formulary ACE inhibitor or Calcium Channel Blocker
Mevacor *(lovastatin)*	maximum doses of **Lescol** and/or **Zocor**
Micardis *(telmisartan)*	any angiotensin converting enzyme inhibitor (e.g. *captopril,* **Prinivil, Accupril**); and **Cozaar**; and **Diovan**
Pepcid *(famotidine)*	*cimetidine;* and *ranitidine*
Prandin *(repaglinide)*	any generic oral hypoglycemic (e.g. *tolazamide, tolbutamide, glipizide, glyburide, chlorpropamide, acetohexamide)*
Pravachol *(pravastatin)*	maximum doses of **Lescol** and/or **Zocor**
Precose *(acarbose)*	any generic oral hypoglycemic (e.g. *tolazamide, tolbutamide, glipizide, glyburide, chlorpropamide, acetohexamide)*

Relafen *(nabumetone)*	any two generic NSAIDS (e.g. *ibuprofen, naproxen, salsalate, choline Mg trisalicylate, piroxicam, sulindac, fenoprofen, meclofenamate, tolmetin, etodolac, diclofenac, ketoprofen, flurbiprofen)*
Rezulin *(troglitazone)*	any generic oral hypoglycemic (e.g. *tolazamide, tolbutamide, glipizide, glyburide, chlorpropamide, acetohexamide)*
Singulair *(montelukast)*	any inhaled anti-inflammatory agent (e.g. **Pulmicort, Flovent, Vanceril/DS, Azmacort**); and an inhaled bronchodilator (e.g. *albuterol,* **Tornalate, Alupent, Proventil HFA,** *ipratropium,* **Atrovent, Combivent, Maxair**)
Tagamet *(cimetidine)*	*cimetidine*
Tarka *(trandolapril/ verapamil)*	any single agent formulary ACE inhibitor or Calcium Channel Blocker; and **Lotrel**
Teczem *(diltiazem/enalapril)*	any single agent formulary ACE inhibitor or Calcium Channel Blocker; and **Lotrel**
Trusopt *(dorzolamide)*	any ophthalmic beta blocker (e.g. *levobunolol, timolol,* **Ocupress, Betimol, Betoptic-S**); and **Azopt**

Vioxx *(rofecoxib)*	any two generic NSAIDS (e.g. *ibuprofen, naproxen, salsalate, choline Mg trisalicylate, piroxicam, sulindac, fenoprofen, meclofenamate, tolmetin, etodolac, diclofenac, ketoprofen, flurbiprofen)*
Vivelle/DOT (*estradiol patch)*	any oral estrogen (e.g. *estradiol, estropipate,* **Estratab, Premphase, Prempra, Premarin**)
Voltaren XR *(diclofenac sodium)*	any two generic NSAIDS (e.g. *ibuprofen, naproxen, salsalate, choline Mg trisalicylate, piroxicam, sulindac, fenoprofen, meclofenamate, tolmetin, etodolac, diclofenac, ketoprofen, flurbiprofen)*
Zantac *(ranrtidine)*	*ranitidine*
Zestril *(lisinopril)*	**Prinivil** *(lisinopril)*

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